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Review Article

Role of Meddra and Oracle Argus Safety in Clinical Data Management and Pharmacovigilance

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A B S T R A C T

Pharmacovigilance and clinical data management are critical components of drug safety and regulatory compliance throughout the drug development lifecycle. The MedDRA (Medical Dictionary for Regulatory Activities) and Oracle Argus Safety play a vital role in standardizing, processing, and evaluating safety data. MedDRA provides a globally accepted, standardized medical terminology that facilitates accurate coding, classification, and analysis of adverse events, ensuring consistency in regulatory reporting across different regions.

Oracle ArgusSafety, a comprehensive pharmacovigilance database system, enables efficient case processing, signal detection, and regulatory reporting. It integrates MedDRA for precise adverse event coding and supports compliance with international regulatory requirements such as those from the FDA and EMA. Together, these tools enhance data quality, improve workflow efficiency, and enable timely detection of potential safety signals.

In clinical data management, the integration of MedDRA and Argus Safety ensures structured data collection, uniform terminology usage, and reliable safety evaluation. This combination supports better decision-making, risk assessment, and ultimately contributes to patient safety. The adoption of these systems represents a significant advancement in modern pharmacovigilance practices, promoting global harmonization and regulatory transparency.

Key words: Oracle Argus Safety, Clinical Data Management, Pharmacovigilance

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INTRODUCTION

To clarify the historical adverse events, pharmaceutical companies have utilized various distinct dictionaries, such as WHO's terminology for adverse reactions, the Thesaurus of adverse reaction terms, or the international classification of diseases. In 1994, the medical dictionary for regulatory activities, known as MedDRA, was established by the pharmaceutical industry in collaboration with regulatory agencies. Initially, the goal was to standardize electronic submissions. MedDRA is structured hierarchically, with the lowest level terms at the bottom, followed by preferred terms, and system organ class at the top (SOC). Initially, events are encoded using the lowest level terms that encompass numerous synonyms and varied spellings of the preferred terms, which are specific to medical entities.

Businesses are not allowed to add new terms that will be further considered for the biannual update, but they are allowed to suggest new terms or change their position in the hierarchy. Each preferred term should have a separate primary SOC in order to verify whether an adverse event is counted just once in the standard summary table. However, they might have specific secondary ones to help with data retrieval.[6] MedDRA: MedDRA is a clinically verified worldwide medical language used for medical products by regulatory bodies and the regulated biopharmaceutical industry. These terms are useful throughout the pre-marketing and post-marketing phases.[7]

Med DRA's past:

There were numerous coding dictionaries in use prior to the International Conference Harmonization (ICH). For instance, the Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) coding system was favored by the Food and Drug Administration. The World Health Organization's Adverse Reaction Terminology and the International Classification of Diseases were two other widely utilized systems.Some businesses even created their own internal terminology. Such a wide range of coding systems made it difficult to compare and pool safety data and put a significant strain on businesses that might have to recode data for submissions to various regulatory areas. A working committee made up of industry representatives and regulatory bodies from the UK, Spain, and France drafted the initial version of MedDRA, also known as MEDDRA[7]. The adoption of this lexicon as the worldwide standard for adverse event coding was proposed at a 1994 conference of the Council for the International Organization of Medical Sciences (CIOMS).The ICH codified the ruling in their M1 interdisciplinary project. Adverse events in the majority of regulatory submissions are now coded using MedDRA, which quickly became the preferred coding system.[8]

Meddra Hierarchy:-[9]

Level (Top → Bottom)	Term Name	Description	Example
Level 1	SOC (System Organ Class)	Broadest classification by organ/system	Nervous system disorders
Level 2	HLGT (High Level Group Term)	Groups related medical conditions	Central nervous system disorders
Level 3	HLT (High Level Term)	More specific grouping of terms	Neurological disorders NEC
Level 4	PT (Preferred Term)	Standard term for a medical concept	Headache
Level 5	LLT (Lowest Level Term)	Most detailed/synonyms	Migraine headache

The goal of MedDRA

- It facilitates the sharing of clinical data through standardization.
- MedDRA is a crucial instrument for product evaluation, monitoring, communication, electronic record exchange, and oversight.[6]
- MedDRA supports human medical products, such as medicines, biologics, vaccines, and drug-device combination products, by coding, retrieving, and analyzing clinical data.

Where is MedDRA utilized?

- Phases 1, 2, 3, and 4 of the clinical trials.
- Reports from clinical studies.
- Safety summaries and individual case safety reports.
- The investigator's mentor.
- Analysis.5 Applications for marketing.
- Publication. Information about prescriptions.
- Promotion.

WHY DOES MEDDRA REQUIRE CODING?

- Different terminologies are used around the world, and coding has been developed to lessen the variety.
  Individual MedDRA nomenclature characterizes an eight-digit number code.
  There are no expressions in the code.
- Codes in a number of electronic submission categories can be used to meet the data range.
- In essence, it is arranged alphabetically by terms that start with 10000001.On the other hand, new terms are enabled successively.

MedDra coding guidelines:[4]

1. Choosing the Lowest Level Term (LLT)

   Always choose the most precise LLT that accurately represents the data that has been reported.

   A Preferred Term (PT) and LLT are directly related.

2. Maintain the Original Meaning

   The precise medical notion described should be reflected in the coding.
   Refrain from changing or misinterpreting what the reporter says.

3. Don't Assume or Assume
4. Refrain from drawing clinical conclusions.
5. For instance, "chest pain" shouldn't be classified as "myocardial infarction."

   Codify any pertinent data Consist of: Symptoms and indicators Diagnoses o Test findings Health issues

6. Make use of the most recent MedDRA version

   To ensure consistency, always use the most recent version.

Managing Several Ideas If a report includes more than one medical concept, code each one independently. For instance, "fever and rash" yields two codes.

7. Take Care When Using Combination Terms If a combination condition has a single MedDRA word, it is preferable that If not, code each component separately.

8. Coding of Primary and Secondary Events Determine the main event (complaint). Additional events should be classified as secondary or supporting words.

9. Coding Consistency Ensure that all research and databases use the same coding procedures. To lessen variability, adhere to regular procedures.

VERSION CONTROL: [11]

In MedDRA, version control refers to the deliberate, recurring update of the language to guarantee that it represents current pharmacovigilance procedures, regulatory requirements, and medical knowledge.
Under the direction of ICH, MSSO maintains MedDRA.
The rationale for the twice-yearly updates to MedDRA
For the following reasons, MedDRA releases are planned every two years, in March and September:

1. Quick Development of Medical Knowledge
   - Adverse drug reactions, new illnesses, and syndromes are constantly being discovered.
   - For instance, new clinical conditions and growing safety concerns Frequent revisions guarantee MedDRA's scientific accuracy.
2. Launch of Novel Medicines and Treatments
   - New vaccines, medications, and biologics are introduced to the market.
   - To code undesirable events, new vocabulary is needed.
   - Updates facilitate reliable pharmacovigilance safety reporting.
3. Harmonization of Regulations Worldwide
   - Pharmaceutical businesses and regulators utilize MedDRA globally.
   - Consistency among nations is maintained by frequent updates. complies with ICH criteria for standardized communication.
4. Ongoing Enhancement through User Input Users all throughout the world submit change requests.

These consist of: Adding new phrases Fixing mistakes Enhancing the hierarchy Biannual updates enable the prompt execution of authorized modifications.

5. Strike a Balance Between Flexibility and Stability Data inconsistency due to too frequent updates
6. Outdated terminology due to too few updates Updates every two years offer the best compromise between:
7. Stability of data Relevance of terminology
   Release Types
   March Release (X.0) → Significant modification
   September Release (X.1): A small update
   Included in every version are:
8. New vocabulary Changed terminology Terms of retirement Modifications to the hierarchy

ORACLE ARGUS SAFETY SOFTWARE [11]

Introduction to Argus: Many pharmaceutical companies have implemented specialized software systems to handle adverse events (AEs) and regulatory submissions due to the increasing demand for thorough drug safety surveillance. Among them, Oracle's Argus Safety Database stands out as a top pharmacovigilance tool utilized by major pharmaceutical companies, government agencies, and contract research organizations (CROs) worldwide. It provides an integrated platform for the effective handling of aggregate reports, signal detection, and individual case safety reports (ICSRs).

Argus Safety is the industry's gold standard since it offers: High Data Accuracy & Standardization, Automation & Efficiency, Wide Industry Adoption, Global Regulatory Compliance, End-to-End Pharmacovigilance Solution, Integration Capabilities.

Argus Modules[12]: -

- Argus Safety (Primary Case Processing).
- Argus Console (Configuration).
- Argus Affiliate (reporting from the local office).

1. The system's central component, the Argus Safety module, is principally in charge of handling cases. Individual Case Safety Reports (ICSRs) can be recorded, evaluated, and managed by users. Workflow management, medical review, coding using standardized terminology like MedDRA, and regulatory reporting to health authorities are all supported by this module. It guarantees adherence to international pharmacovigilance standards, including those set forth by organizations such as the European Medicines Agency and the U.S. Food and Drug Administration.
2. System administration and configuration are handled by the Argus Console module. Business rules, workflows, user roles, security settings, and reporting configurations can all be defined by system administrators. By enabling the customization of data fields, coding dictionaries, and case processing logic, this module guarantees that the Argus system complies with organizational and regulatory standards.
3. The Argus Affiliate module makes it easier for local affiliate offices and global headquarters to exchange safety data. By enabling local entry and management of adverse event data by regional offices while maintaining synchronization with the central database, it facilitates decentralized reporting. Multinational pharmaceutical businesses that must adhere to national pharmacovigilance laws will find this program especially helpful.

- Adherence to FDA regulations (21 CFR Part 11) [13]

- About 21 CFR Part 11:21 CFR Part 11 establishes standards for electronic signatures and records, guaranteeing that they are reliable, trustworthy, and on par with paper documents.

- How Argus Complies with FDA Requirements: Oracle Argus Safety uses the following methods to comply with FDA regulations:

- Electronic Signatures & Records (ERES):

Argus facilitates the processing and reporting of cases using safe electronic documents and legally recognized electronic signatures.

Audit Trails: To ensure traceability, the system keeps an exhaustive audit trail of all data entries, revisions, and user actions.

System Validation: Argus is a proven system that guarantees pharmacovigilance data correctness, consistency, and dependability.

Access Control & Security: Unauthorized access is prevented via password controls, role-based access, and authentication methods.
Data confidentiality and integrity:
Data integrity is preserved by controlled workflows, secure login, and encryption (HTTPS/SSL). • Regulatory Reporting Compliance: Complies with FDA safety report formats, including IND, MedWatch, and CIOMS.

4. Adherence to EMA Guidelines
   The European Medicines Agency's (EMA) regulatory framework
   The European Medicines Agency mandates adherence to:

- Computerized systems in EudraLex Volume 4 (Annex 11)
- Good Pharmacovigilance Practices (GVP) of the European Union
  ICH E2B(R3) for electronic reporting of cases How Argus Fulfills EMA Requirements Compliance with EU Annex 11: Argus offers verified computerized systems with data security, user control, and audit trails that are in line with Annex 11.
- GVP Compliance: In accordance with EU GVP regulations, the system permits appropriate case processing, signal detection, and risk management.
- E2B(R3) Electronic Reporting: Individual Case Safety Reports (ICSRs) can be electronically transmitted to EMA and other authorities in a standardized manner using Argus.

To comply with changing EMA and international standards, the system is updated on a regular basis.

5. Extra Features for Global Compliance • Adherence to ICH regulations (E2B, GCP)

- Assistance with several regulatory bodies (FDA, EMA, PMDA, MHRA)

- Automated safety procedures that guarantee on-time submissions

- The Case Processing Workflow

- Inspection preparedness and audit assistance 14
  Case Receipt & Triage: Assessing the "Validity" of a Case (4 Pillars)
  Every reported case in pharmacovigilance must satisfy the following four requirements in order to be deemed legitimate:
  Identifiable patient

- Identifiable reporter
  Potential medication or product

- Adverse reaction

CASE INTAKE IN ORACLE ARGUS SAFETY ENTAILS:

Getting reports (literature, clinical trials, and spontaneous)
Conducting a duplicate check
Assigning a case number → The case is deemed valid for processing (ICSR) if all four components are present.
Data Entry: Inputting Product and Patient Information into Argus

Structured tabs are used to enter data:

Patient characteristics (weight, age, and gender)
Product information (drug name, dosage, and method)
Details of the event (verbatim description)
Lab results and medical history
At this point: Ensures accurate and comprehensive data capture prior to coding; terms are input verbatim (reported terms).

Medical Coding: Using Argus's MedDRA Browser

This is the main phase in the MedDRA workflow.
Argus's integrated MedDRA is used for coding.

PROCEDURE:

The MedDRA browser's verbatim term → search
Make the right choice:
Lower Level Term, or LLT
Mapped to PT (Preferred Term) automatically
For instance:
"Severe headache" => LLT: Severe headache → PT: Headache
Coding may be:

Auto-coded (recommended by the system)

Coded by hand (user selection) guarantees the use of uniform international terminology

Causality Assessment: Determining Whether the Event Was Caused by the Drug

- Assesses the connection between medication and adverse events
- Typical technique:
- Categories of the Naranjo Scale:
- Based on: Definite, Probable, Possible, Doubtful
- Temporal connection

Dechallenge and re-challenge

Alternative causes A medical reviewer often completes this phase.
Medical and Quality Review: Verifying Accuracy
The case is reviewed at several levels:

QUALITY ASSESSMENT:

Data completeness Accurate MedDRA coding uniformity in all fields
Medical Evaluation: Clinical assessment of the case
Evaluation of seriousness Final proof of causality
Guarantees: Adherence to regulations and superior safety information Reporting and Submission: Creating MedWatch or CIOMS Forms

The completed case is ready to be submitted to regulatory bodies.
Typical Formats for Reports:

The CIOMS Form (for worldwide reporting)

The FDA MedWatch Form
Med DRA-coded phrases are automatically generated in Argus using coded data.

ICSR submission

Signal identification

Combine reports.
FINAL WORKFLOW: Quality & Medical Review → Data Entry → MedDRA Coding → Causality Assessment → Case Receipt & Triage → Reporting & Submission

Argus's Use of the MedDRA Browser 15
Argus incorporates the MedDRA browser for effective term coding and selection.Look up terms verbatim (reported)
o Show the entire MedDRA hierarchy: LLT (Lowest Level Term) Preferred Term, or PT HLT → HLGT → SOC
Enables: Search for synonyms A partial word search
Navigating through hierarchies:

Reported term: "Stomach pain" → LLT: Stomach discomfort → PT: Abdominal pain → SOC: Gastrointestinal disorders guarantees that the most medically suitable standardized phrase is chosen.
Argus's Auto-Encoding (Auto-Coding) Features To increase productivity, Argus offers auto-encoding capabilities.
How It Operates:

The MedDRA dictionary and the system match terms verbatim.

Automatically recommends the nearest LLT/PT

Applications: Dictionary matching Mapping synonyms Coding patterns from the past

Types: Automatic assignment via full auto-coding
Recommended coding: user approval needed Benefits: Minimizes manual labor Boosts reliability expedites the processing of cases.

How Inaccurate Coding Affects Signal Detection
The process of finding new safety hazards is known as signal detection. This process can be greatly impacted by incorrect MedDRA coding:
IMPACT:
1. Signal Dilution Different coding for the same event Information is dispersed among several phrases
2. Inaccurate Signals Incorrect coding could lead to fake trends.
3. Missed Signals Real safety problems go unnoticed
4. Risk to Regulation
Inaccurate reporting to authorities Failure to follow instructions; for instance, "heart attack" could be mistakenly coded as "chest pain"; a serious signal could be overlooked
Precise coding is essential for: Data aggregation Analysis of statistics
Risk control
Anatomical Therapeutic Classification's (ATC) Function in Argus
Argus uses the ATC Classification System in addition to MedDRA.
categorizes medications according to: Use in therapy Pharmacological action, Chemical characteristics

Connectivity to MedDRA:

Adverse events are coded by MedDRA →
The ATC classifies drugs Collectively, they aid in:
Drug-event connection signal detection Combined reporting Analysis of drug safety Future Trends & Pharmacovigilance Conclusion Cutting-edge technology like artificial intelligence are driving pharmacovigilance in the future.
AI is being investigated to automate coding using MedDRA in systems such as Oracle Argus Safety, where machine learning algorithms can precisely match standardized MedDRA phrases with verbatim adverse event terms. This maintains coding accuracy while lowering manual labor, increasing consistency, and accelerating case processing.
The utilization of actual evidence, particularly from digital and social media platforms, is another new trend. Potential adverse drug reactions can be found by analyzing patient-reported data from online sources. By coding these real-world inputs using MedDRA nomenclature, safety alerts that might not be picked up by conventional reporting systems can be detected earlier.

CONCLUSION

Standardized data collection, precise analysis, and efficient signal detection are guaranteed by the integration of MedDRA coding and drug classification systems, such as the ATC Classification System, within Argus. When combined,

these methods enhance the identification of drug-related concerns and facilitate prompt regulatory decisions, eventually improving patient safety and safeguarding public health.

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