SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
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SRMC PHARMVIGIL

A Passion for Better Medicine

Pharmacovigilance Newsletter

Department of Pharmacology

SRMC & RI
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SRI RAMACHANDRA
MEDICAL COLLEGE AND RESEARCH INSTITUTE

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Pharmacovigilance Newsletter

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Sri Ramachandra Medical College & Research Institute
SRIHER (DU), Porur, Chennai - 600116

News Letter Insights | **Page No:**

MESSAGE FROM EDITOR

Dear Readers,
Warm Greetings to one and all

It is with great pride and pleasure that we present **"SRMC PHARMVIGIL"** Newsletter, Volume 5, Issue 1 (January 2026), covering the index period from July 2025 to December 2025, on behalf of the SRMC–Adverse Drug Monitoring Centre (AMC), Department of Pharmacology, Sri Ramachandra Medical College & Research Institute (SRMC & RI), SRIHER.

This issue brings together a thoughtfully curated selection of articles highlighting contemporary and evolving dimensions of pharmacovigilance. The thematic focus spans the social media and internet pharmacovigilance monitoring, regulatory pharmacovigilance challenges, guidelines for advanced therapy medicinal products (gene, cell, tissue- based therapies), decentralized clinical trials and pharmacovigilance, orphan drug and rare disease pharmacovigilance challenges, phenoconversion- the drug –drug- gene interaction, vigilance for in vitro diagnostic devices and an overview of recent FDA-approved drugs. Collectively, these contributions underscore the critical importance of robust pharmacovigilance systems in ensuring patient safety across diverse healthcare settings.

To further enrich reader engagement and promote active learning, this issue also features interactive sections including a crossword, unscramble, and creative elements such as an illustrative drug safety cartoon and poem, reinforcing pharmacovigilance concepts in an innovative and reader-friendly manner.

The Adverse Drug Monitoring Centre at Sri Ramachandra Medical College continues to play an active role in sensitizing and educating healthcare professionals across multiple specialties on the importance of timely and accurate adverse drug reaction (ADR) reporting. Through sustained awareness initiatives and capacity-building activities, the centre remains committed to supporting the objectives of the Pharmacovigilance Programme of India (PvPI) and the WHO–Uppsala Monitoring Centre (WHO-UMC) by contributing high-quality Individual Case Safety Reports (ICSRs), thereby strengthening the global drug safety database. We extend our sincere appreciation to the Department of Obstetrics & Gynecology, SRMC & RI, SRIHER, for reporting the highest number of ADRs during the July–December 2025 period. This commendable contribution reflects a strong culture of interdepartmental collaboration and shared responsibility towards medication safety, which ultimately translates into improved patient care outcomes.

Happy fruitful learning!

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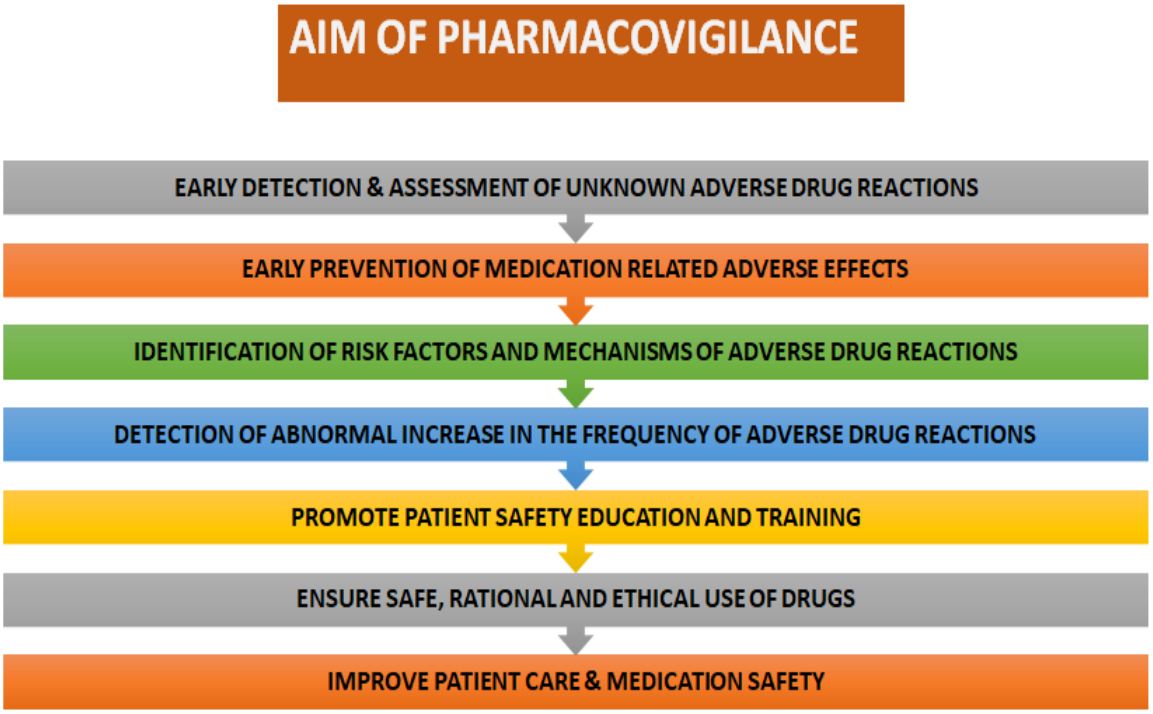
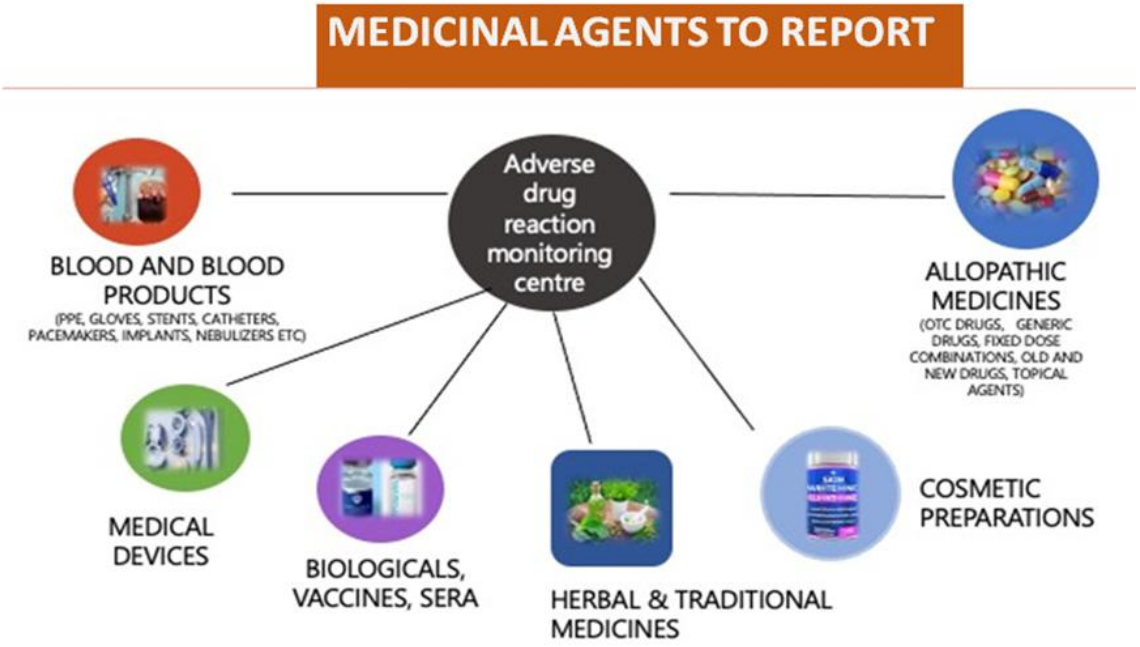
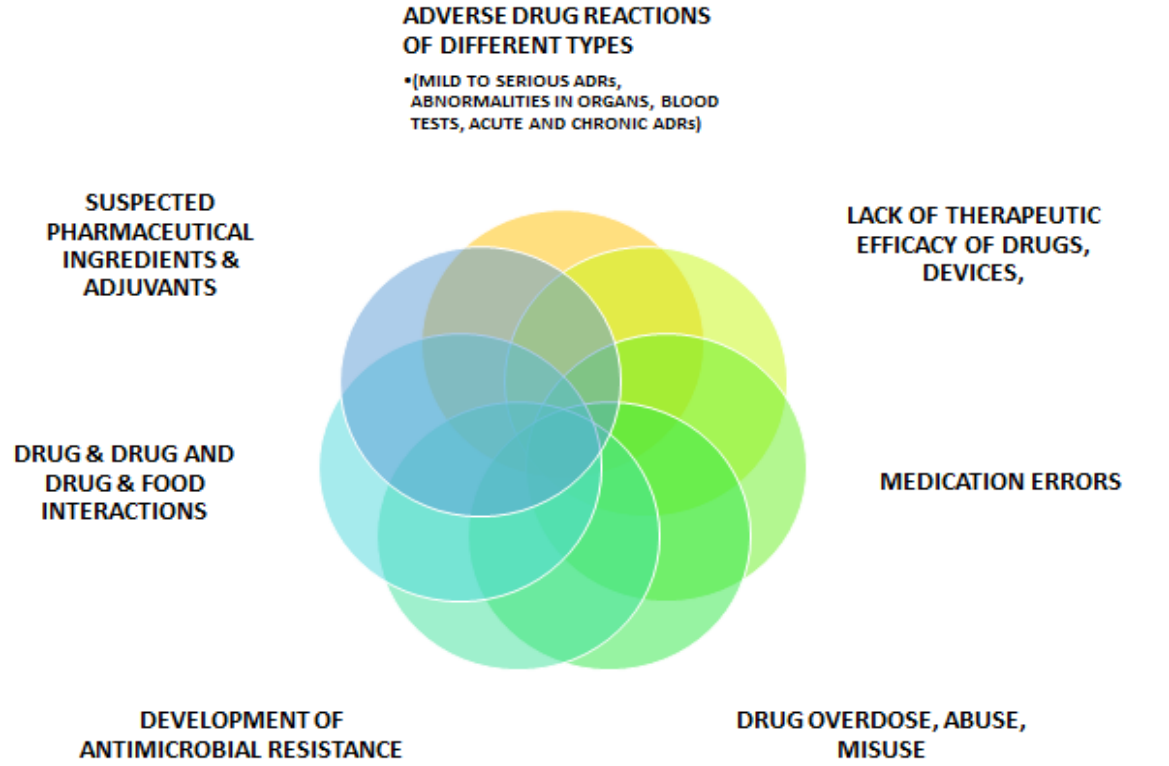
REITERATING ALL ABOUT PHARMACOVIGILANCE





FACTORS TO REPORT FOR REPORTING ADR



SOCIAL MEDIA AND INTERNET PHARMACOVIGILANCE MONITORING

Dr. V.P. Karthik
Associate Professor

Introduction

Pharmacovigilance (PV), the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem, has evolved tremendously with the digital revolution. Traditionally, pharmacovigilance relied on spontaneous reporting systems, clinical trials, and published literature. However, the rise of **social media and internet-based platforms** has introduced a new and dynamic source of real-world data that can transform post-marketing surveillance. In today's connected world, patients, caregivers, and healthcare professionals frequently share their experiences about medicines and side effects on platforms such as **Twitter (X), Facebook, Instagram, Reddit, YouTube**, and specialized health forums like **Patients LikeMe** or **Drugs.com**. These unfiltered and real-time discussions represent a vast reservoir of potentially useful information for early **signal detection** in pharmacovigilance.

The Rationale for Using Social Media in Pharmacovigilance

Social media offers several advantages compared to traditional pharmacovigilance systems:

1. **Timeliness:** Adverse events may be mentioned on social platforms **much earlier** than they are formally reported through traditional systems.
2. **Wide Reach:** Millions of users across demographics, geographies, and socioeconomic groups provide a diverse dataset.
3. **Patient-Centric Insights:** Posts often include **patient narratives**, emotional tones, and quality-of-life details not typically captured in ADR forms.
4. **Access to Underreported Events:** Certain adverse events that patients may hesitate to discuss with physicians — for example, those involving sexual or psychiatric side effects — are sometimes openly discussed online.

By analysing this data, regulatory agencies and pharmaceutical companies can gain a **complementary view** of medicine safety in real-world use.

Techniques and Tools for Internet Pharmacovigilance

Extracting meaningful information from the vast, unstructured, and noisy data on social media requires **advanced computational tools**. Key technologies include:

- **Natural Language Processing (NLP):** Converts informal language posts into analysable text, identifying drug names, symptoms, and relationships between them.
- **Machine Learning (ML) Algorithms:** Used to automatically detect patterns, classify ADR-related posts, and reduce false positives.

- **Sentiment Analysis:** Determines public emotions or attitudes toward a specific drug, helping assess its safety perception.
- **Data Mining and Big Data Analytics:** Facilitate large-scale screening of millions of posts across platforms.

Regulatory bodies such as the **U.S. Food and Drug Administration (FDA)** and the **European Medicines Agency (EMA)** have initiated pilot projects exploring **AI-driven social media signal detection**. For instance, the FDA's *MedWatcher Social* project demonstrated the feasibility of identifying safety signals for drugs like statins and antidepressants through Twitter data.

Applications in Pharmacovigilance

1. **Early Signal Detection:** Social media monitoring can detect emerging drug safety issues before traditional reporting systems capture them.
   Example: Early public discussions about **fluoroquinolone-induced tendon rupture** appeared on online forums years before regulatory warnings were issued.
2. **Post-Marketing Surveillance:** Continuous tracking of drug mentions allows long-term safety evaluation beyond the limited scope of clinical trials.
3. **Benefit-Risk Assessment:** Real-world patient feedback helps understand not only adverse events but also **treatment satisfaction and tolerability**.
4. **Public Health Monitoring:** During pandemics or vaccination drives, social media can be used to monitor public sentiments and detect clusters of reported side effects, as seen with **COVID-19 vaccine pharmacovigilance**.

Challenges and Limitations

Despite its potential, social media-based pharmacovigilance faces several challenges that limit its routine implementation:

1. **Data Quality Issues:** Posts are often **unverified, incomplete, or ambiguous**, lacking critical details like dose, duration, or concurrent medications.
2. **False Positives:** Automated systems may wrongly classify unrelated discussions as ADRs (for example, "This headache is killing me" may be flagged incorrectly).
3. **Ethical and Privacy Concerns:** Extracting and analyzing user data raises questions about **consent**, **data ownership**, and **confidentiality**.
4. **Lack of Standardization:** There is no globally accepted regulatory guideline on how to validate or integrate social media signals into official PV systems.
5. **Language and Cultural Variability:** Posts in different languages, slang, and idiomatic expressions pose difficulties for text mining.
6. **Regulatory Acceptance:** Current regulatory frameworks still consider social media as a **supplementary** data source, not a primary evidence base.

Regulatory Perspectives and Initiatives

- **U.S. FDA:** Conducted several feasibility studies through its *Sentinel* and *MedWatcher Social* programs. The agency recognizes the potential of digital data sources but emphasizes the need for validation and ethical compliance.
- **European Medicines Agency (EMA):** Published a reflection paper (EMA/53746/2024) highlighting the role of digital data, including social media, in future pharmacovigilance strategies.
- **WHO-UMC:** Encourages member states to explore social media analytics as an adjunct to spontaneous reporting systems such as **VigiBase**.

- **India's PvPI (Pharmacovigilance Programme of India):** Has begun considering digital tools for public awareness and signal detection, though social media monitoring is still at a pilot stage.

Best Practices and Future Directions

To harness the full potential of social media pharmacovigilance, certain best practices must be followed:

1. **Data Triangulation:** Correlate social media signals with validated sources like VigiBase, EudraVigilance, or FDA Adverse Event Reporting System (FAERS).
2. **Algorithm Transparency:** Ensure AI models are explainable and periodically validated by human experts.
3. **Ethical Framework:** Develop strict policies for data use, ensuring anonymity and compliance with data protection laws (e.g., GDPR).
4. **Regulatory Guidance:** Establish standardized methods for signal validation and reporting.
5. **Capacity Building:** Train pharmacovigilance professionals in digital analytics, AI tools, and ethical handling of online data.

Looking forward, social media is expected to play an **increasingly proactive role** in pharmacovigilance. Integration of **real-time monitoring dashboards**, combined with **AI-driven risk prediction models**, could make post-marketing surveillance more dynamic and patient-centred.

Conclusion

Social media and internet-based pharmacovigilance represent a paradigm shift in drug safety monitoring. They offer unparalleled opportunities to detect emerging signals early, engage patients directly, and complement traditional systems with rich, real-world insights. However, the path forward requires addressing challenges related to data quality, ethics, and regulatory acceptance. As digital technologies mature and regulatory frameworks evolve, **social media monitoring will likely become a cornerstone of next-generation pharmacovigilance**, ensuring safer medicines and stronger public trust in healthcare systems.

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REGULATORY PHARMACOVIGILANCE CHALLENGES & GUIDELINES FOR ADVANCED THERAPY MEDICINAL PRODUCTS (GENE, CELL, TISSUE- BASED THERAPIES)

Dr. Najma Sherin
Senior Resident

Introduction:

They are medicines for human use that are based on genes, tissue engineering or cells. Advanced therapy medicinal products (ATMPs) can be classified into three main types. They are

- Gene therapy medicines
- Somatic-cell therapy medicines
- Tissue engineered medicines
- Combined Advanced therapy medicinal products

Therefore, pharmacovigilance for ATMPs must go beyond conventional drug-safety frameworks; it requires customised risk management, longer-term supervision, and trustworthy mechanisms to track goods from donor to patient. With reference to global best practices, this article outlines the regulatory pharmacovigilance concerns unique to ATMPs and offers practical advice for Indian regulators, producers, and physicians.

Key pharmacovigilance challenges and regulatory approaches for ATMPs:

Challenge	Why it matters	Recommended actions (regulatory & operational)
Long-term safety monitoring	ATMPs can produce delayed or lifelong effects (e.g., incorporation mutagenesis, late immune reactions). Short follow-up misses important harms.	Require product-specific Long Term Follow Up in Risk Management Plans (RMP); mandate ≥ annual reporting, registry enrolment, and predefined biomarker panels. Clinically: schedule follow-up visits, maintain contact pathways, and collect standardized outcome data.
Traceability & batch linkage	Single-patient or small batches and donor materials need precise linkage to identify root-cause of events. Poor traceability delays recalls and safety analyses.	Mandate unique product identifiers (UPI), strict chain-of-custody recordkeeping, and electronic batch linkage to patient records. Operationally: barcode/QR tracking and centralized registry fields for batch data.
Immunogenicity, off-target & delayed effects	Mechanistic risks (immune reaction, off-target editing) may present atypically and late, complicating detection and response.	Require pre-specified assays for vector persistence and immunogenicity in RMPs; include plans for molecular surveillance. Clinicians should collect and submit samples to reference labs per protocol.
Causality assessment complexity	Small populations, comorbidities and disease progression make it difficult to attribute events to product or underlying disease.	Establish multidisciplinary expert review panels and standardized causality frameworks for ATMPs. Use mechanistic biomarkers and centralized case review for ambiguous events.

Data fragmentation & limited RWD	The separation of lab systems, registries, and Electronic Health Records reduces completeness and delays signal detection.	Create a national ATMP registry with interoperability standards; require MAHs to submit post-marketing data. Operational: adopt standardized case-report forms, enable EHR-registry linkage and routine data extracts.
Manufacturing variability & inspections	Small process changes can alter safety; inconsistent oversight risks drifting product quality.	Enforce strict change control, Good Manufacturing Practice for ATMPs, and conditional approvals tied to manufacturing transparency. Regulatory inspections and public reporting of major changes.
Reporting culture & capability gaps	Clinicians may not recognise or report delayed/atypical events; centres may lack Pharmacovigilance (PV) infrastructure.	Designate PV focal points at ATMP centres, provide training and simplified reporting pathways, and require reporting timelines in licence conditions. Provide feedback loops to reporters.

International regulatory guidance – a concise view:
International regulators have recognised these challenges and issued guidance that can inform Indian practice:

- The **European Medicines Agency (EMA)** provides ATMP-specific guidance on safety, efficacy follow-up and risk management that emphasises integrated risk-management plans and registries.
- The **U.S. Food and Drug Administration (FDA)** has guidance documents on long-term follow-up for gene therapies and post-marketing expectations for cellular and gene products.
- **International Council for Harmonisation (ICH)** pharmacovigilance planning (E2E and related guidance) supplies general frameworks for RMPs, signal detection and post-authorisation safety planning.

Operational tools and methods:

- ✓ Product safety registries: Product or disease-specific registries that combine results for uncommon indications.
- ✓ Real World Data (RWD) signal detection: To find signals in tiny datasets, apply innovative analytics and probabilistic techniques.
- ✓ Molecular/biomarker surveillance should incorporate assays that can detect vector persistence , incorporation events, or abnormal clonal proliferation.
- ✓ Multidisciplinary Safety Review Boards: Regular evaluations by statisticians, cell biologists, doctors, and regulators.

Conclusion:
ATMPs are revolutionary, but they also pose a challenge to conventional pharmacovigilance models. We can implement practical, risk-proportionate frameworks that include national registries, improved traceability, international guidelines, and clinician involvement. In addition to protecting patients, a proactive, well-funded pharmacovigilance program will enable India to properly profit from these innovative treatments.

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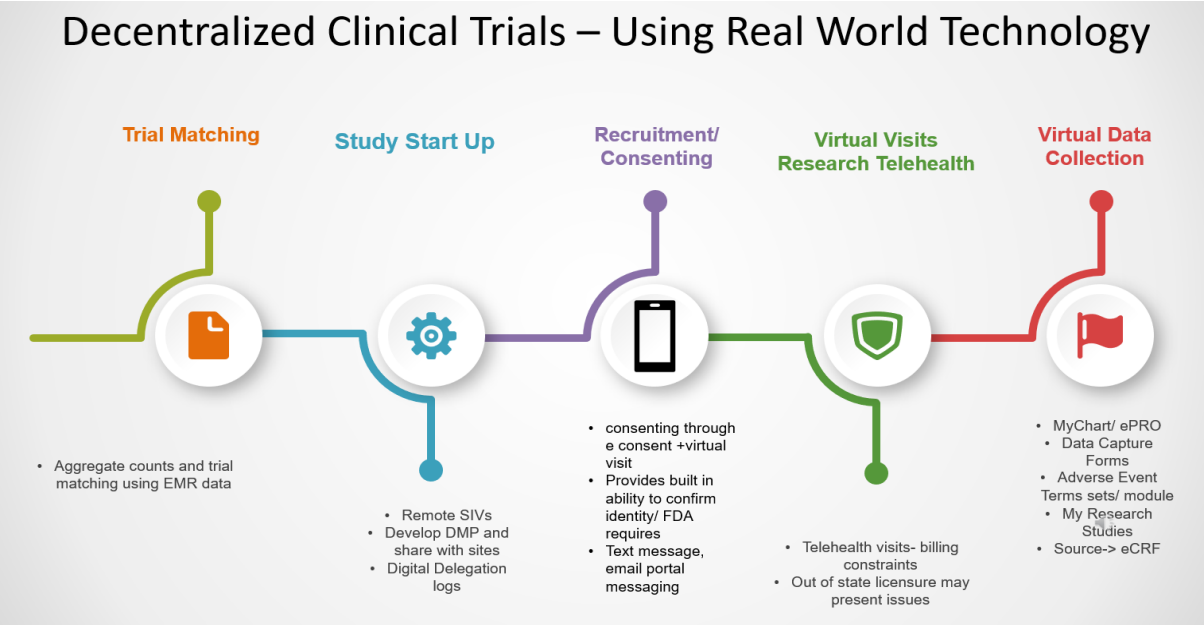
DECENTRALIZED CLINICAL TRIALS (DCTS) AND PHARMACOVIGILANCE

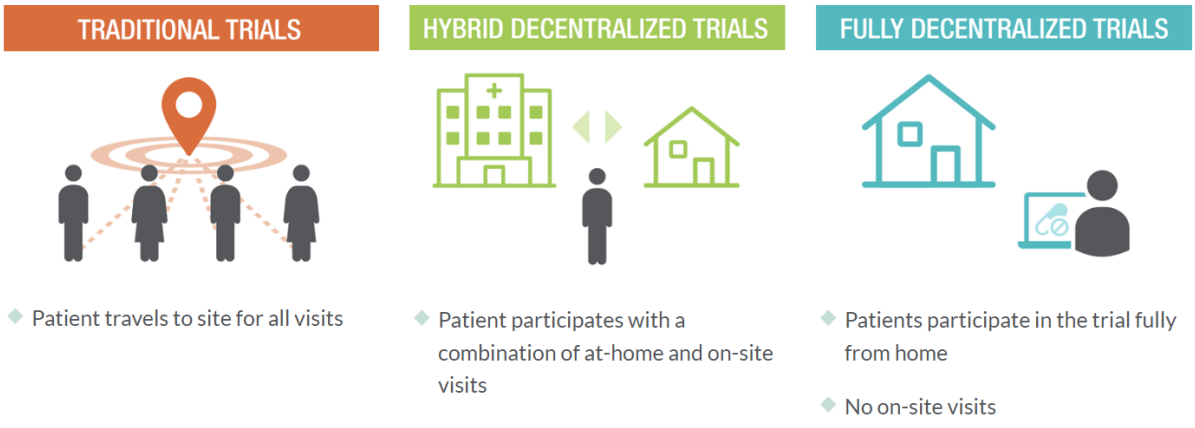
Dr.K.Karthika,
Associate Professor

A Decentralized clinical trial (DCT) is a clinical trial in which some or all trial-related activities occur at locations other than traditional clinical trial sites like hospitals or clinics. They are also known as "Direct-to-participant trials" or "virtual" studies.



Some or all trial activities, such as data collection and participant visits, take place at a participant's home, local pharmacy, or community clinic. DCTs may use software applications and digital solutions, such as telemedicine for visits, wearable devices to collect real-time data, mobile apps for patient reporting, and electronic health records. The patient may receive the medicines and materials directly at home. The monitoring may be done by local health care professionals, allowing convenience and decreasing the number of visits.

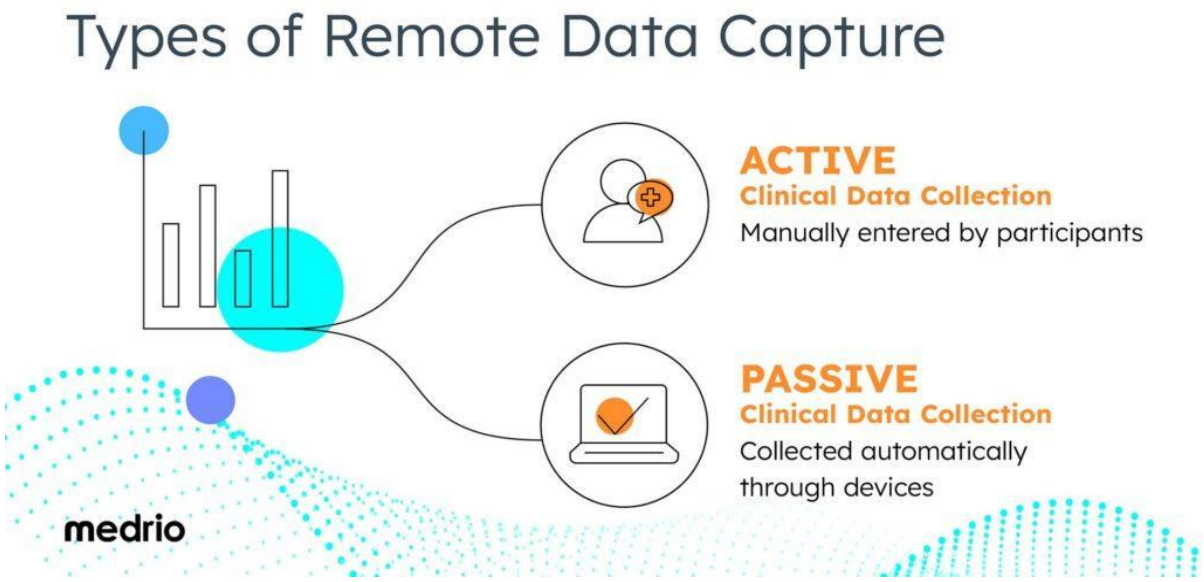
There are three types of clinical trials – Traditional (Fully Centralized), Hybrid and Fully Decentralized trials.



Benefits of DCTs:

- Ω Ability to include patients in rural areas, patients from underprivileged geographies, or those with limited travel possibilities.
- Ω By lowering barriers to participation, DCTs can help researchers recruit a more diverse patient population.
- Ω More flexibility for patients, which in turns leads to higher retention and better satisfaction with the trial participation.
- Ω DCTs can generate more representative, real-world data by collecting information from participants in their normal environment.
- Ω Helps prevent missing data.
- Ω Can be performed at larger scale, spanning across centers and countries to enhance diversity and robustness of trials.

The Digital Health Technologies (DHT) used in DCT are Telemedicine, wearable sensors, mobile apps, electronic health records (EHRs), and direct-to-patient drug delivery. They provide novel opportunities to obtain clinical trial data directly from patients (eg, biomarkers, performance of activities of daily living, sleep, vital signs) wherever they may be (eg, home, work, outdoors). They help to make continuous or frequent measurements of clinical features, to record or measure novel clinical features that could not be captured during traditional study visits (e.g. - tremors), to provide broader pictures of how participants feel or function in their daily lives and to decentralize clinical trial activities by obtaining clinical data from study participants remotely.



Pharmacovigilance for DCTs involves adapting safety monitoring to a remote model, using digital tools to track adverse events (AEs) via telehealth, electronic consent, electronic Clinical Outcome Assessments (eCOA), and connected sensors. It is participant centric - shifts the burden of reporting to the participant.

Challenges in Pharmacovigilance of DCTs:

- ❖ Managing multiple data systems and vendors – increases complexity and cost
- ❖ Challenges in consolidation of data at the time of document preparation.
- ❖ Reconciliation of data can potentially take longer.

- Ensuring data reliability and managing potential variability compared to traditional trials.
- Submission delays.
- Inspections & Audits become more complex.
- Partner Notifications/Exchange of Information, additional tracked activities.
- Coordinating activities across different locations.
- Logistical and chain-of-custody issues: the need to ensure the stability and proper tracking of investigational products shipped directly to patients.
- A large percentage of the world population does not have access to WiFi, cellular, or personal mobile devices. Some people may have access to technology but don't have the knowledge or confidence to fully use it.
- Patients may find it difficult to use new devices. We can overcome this by using apps and devices that the patient knows already [Bring Your Own Device – BYOD technology].
- DCTs face greater data protection challenges. Therefore, cyber security must be taken to protect clinical trial data, personal data, and information.

Solutions for a centralized safety system:

- **Technical agreements:** Clear technical agreements are essential to define responsibilities and data exchange processes between different systems and vendors.
- **Safety management plans:** Develop comprehensive safety management plans specifically for the decentralized model.
- **Standard operating procedures (SOPs):** Establish centralized SOPs with detailed work instructions to ensure consistency across all decentralized activities.
- **Safety database:** Implement a validated, centralized safety database to process and monitor safety data from all decentralized sources.
- **Data exchange:** Ensure the safety database can seamlessly exchange data with other systems, such as the Electronic Data Capture (EDC) system, to provide a complete picture of trial safety
- **Automated Alerts**: Generating alerts for any irregularities, such as dosing errors or supply chain disruptions, that could impact patient safety.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) revised its technical guidance on Good Clinical Practice (GCP) to accommodate trial activities which take place in decentralized settings. The US FDA, the European Medicines Agency (EMA), the National Medical Products Administration (NMPA) of China, Swedish Medical Products Agency (SMPA), Denmark Medical Agency (DKMA), and Swissmedics have issued their own guidance documents and recommendations for the design and conduct of DCTs. Hence, the pharmaceutical companies should engage early with the regulatory agencies when planning to integrate DHTs into a clinical investigation to design a trial that will provide meaningful results.

Digital health technologies (DHT) are reshaping the world of clinical trials. Trials are becoming more convenient as data can be collected where participants live and work. DHTs can measure the health outcomes that matter most to patients, which means we can better evaluate whether treatments are making a meaningful difference to patients. Pharmacovigilance too needs to evolve to accommodate these latest trial designs and their unique challenges.

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COUGH SYRUP TRAGEDIES – LESSONS LEARNT

Dr.Balaji Rathnam K
Senior Resident

The Coldrif tragedy that unfolded in the Chhindwara district of Madhya Pradesh brought both pharmaceutical regulators and manufacturers to a standstill and ranks amongst the most significant drug safety mishaps in recent history. Between September and early October 2025, several children aged mostly between 1 to 5 years presented with a pattern of rapid-onset acute kidney injury (AKI) which was characterised by anuria, vomiting, metabolic acidosis, convulsions and encephalopathy. Despite intensive care, several children succumbed to this deadly disease pattern. The officially confirmed fatalities varied by date across state health bulletins, rising from 9 in the first week of October to around 21-24 by the end of the month. However , there was a common factor lurking beneath all these cases , being a common epidemiological link – the fact that all the affected children had consumed Diethylene Glycol (DEG) contaminated Coldrif Cough syrup – a fixed dose combination of Paracetamol, Chlorpheniramine maleate and Phenylephrine. This fits into the trend of previous cough syrup tragedies involving adulterants like DEG.

The Coldrif cough syrup tragedy

In September 2025 , in the Parasia block of Chhindwara district in Madhya Pradesh – a disturbing pattern emerged among children (mostly below 5 years) who had recently been treated for minor respiratory symptoms (cough , cold or fever). Instead of recovery , they progressed rapidly to acute kidney failure presenting with vomiting , oliguria or anuria , metabolic acidosis , convulsions. As the death toll rose, there came a realisation of an underlying sinister commonality to these cases – the clinicians in Parasia first noticed that multiple children who were otherwise healthy and had only minor respiratory symptoms developed a common toxidrome : abrupt anuria, rapidly rising creatinine, severe metabolic acidosis, and progressive encephalopathy. On interviewing the concerned families - a common history of consumption of the same cough syrup (Coldrif) shortly before collapse was noted. This uniform medication history immediately raised suspicion, prompting the district health team to inspect leftover containers from homes, check the previous clinic prescriptions, and then ultimately trace the suspect cough syrup.

The Fallout – immediate aftermath of the tragedy

As investigation continued, state and national drug regulators initiated sampling of Coldrif from market supply chains. The key findings were:

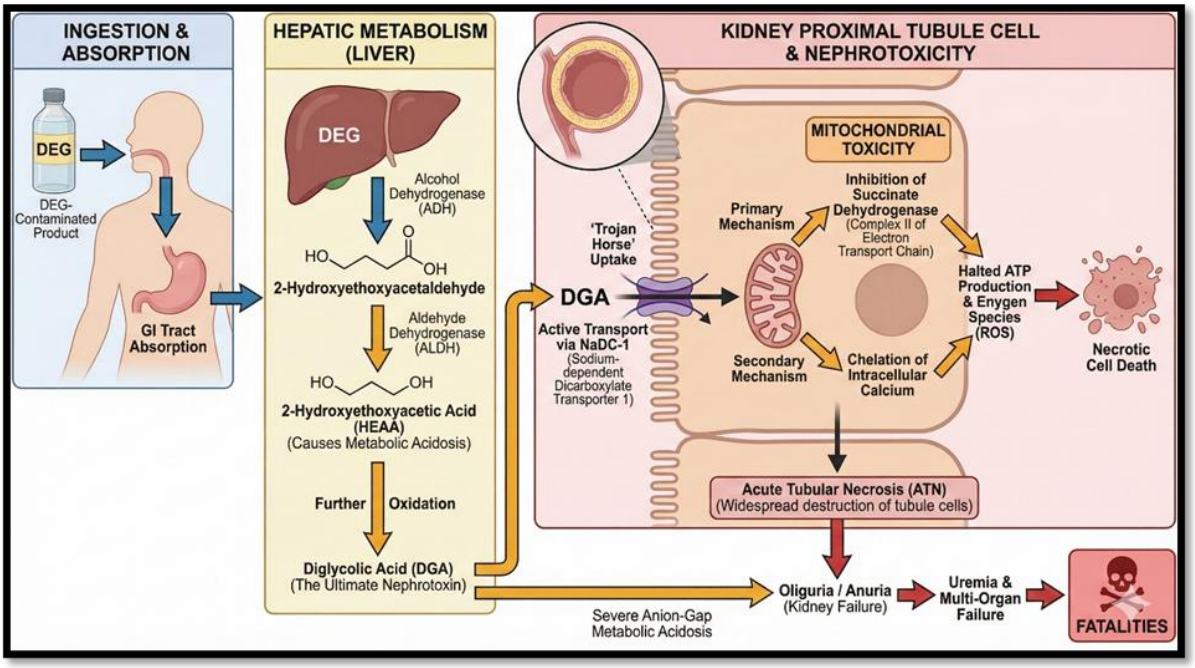
- The contaminated batch was identified as Batch No. “SR-13” (manufactured in May 2025, expiry April 2027), manufactured by Sresan Pharmaceuticals in Kancheepuram, Tamil Nadu.
- Laboratory analysis revealed that this batch contained a **very high concentration of Diethylene Glycol (DEG)** — approximately **48.6% w/v**, far above the permissible limit (0.1%).
- Following confirmation of DEG contamination, the facility was immediately sealed, leading to the permanent cancellation of the manufacturing licence. Several arrests were made in connection with this tragedy - including the owner of the manufacturer company , laboratory staff, chemist , distributor as well as a local paediatrician.

Following these actions, several states took regulatory action (suspension / recall / investigation) .The CDSCO and state regulators launched a massive "risk-based sampling" drive. This identified two other brands of cough syrups with confirmed Diethylene Glycol (DEG) contamination.

Product Name	Manufacturer	Validated DEG Level	Status
Coldrif	Sresan Pharmaceuticals (Tamil Nadu)	48.6%	Lethal. Effectively industrial solvent in a bottle.
Respifresh-TR	Rednex Pharmaceuticals (Gujarat)	1.34%	Toxic. Sufficient to cause renal injury in infants.
Re-Life Syrup	Shape Pharma (Gujarat)	0.62%	Unsafe. Above the pharmacopoeial limit of 0.10%.

The killer toxin Diethylene Glycol (DEG) – mechanism underlying the devastation

Diethylene Glycol is a toxic industrial chemical present in products like antifreeze and brake fluids. However, due to similar physical properties to safe pharmaceutical solvents like Glycerine & Propylene Glycol and hence it can be illegally used as a cheap substitute and adulterant. The pharmacological basis for toxicity is as follows:



Root Cause Analysis

- **A failure in Vendor Assurance and Raw Material Identity Testing:** The manufacturers accepted barrels of "Propylene Glycol" based solely on the vendor's paper Certificate of Analysis (CoA) without performing the mandatory in-house Gas Chromatography (GC) test to identify DEG present.
- **Supply Chain Vulnerability:** Due to the price disparity between industrial DEG and pharmaceutical-grade Propylene Glycol, unscrupulous solvent traders can mislabel barrels, effectively introducing a "chemical Trojan horse" into the factory.

Regulatory Response & Safety Alerts – What needed to be enforced?

A. State Level Enforcement:

- Madhya Pradesh and several other states such as Uttar Pradesh , Kerala enforced strict **"Stop Sale / Stop Distribution"** orders on implicated products (implicated batches such as Batch SR-13 of Coldrif were seized where identified).
- Tamil Nadu: Banned sales of products and r**evoked the manufacturing licence** of the implicated facility (Sresan Pharmaceuticals) and ordered the plant sealed pending a complete Good Manufacturing Practices audit (Schedule M).
- Several State Drug Control Authorities such as Maharashtra and Telangana ordered seizure / quarantine of stocks from wholesale and retail outlets, and directed tracing of distributed/ sold bottles.

B. DGHS Clinical Advisory:

The Directorate General of Health Services (DGHS) issued directives to the State Authorities regarding rational use of cough syrups in children:

1. **< 2 Years**: Cough syrups should not be used.
2. **2–5 Years**: Cough syrup use to be restricted -only under specific clinical prescription; Over the counter sale discouraged

- It also reiterated the earlier notice of the mandate stating that FDC of Chlorpheniramine maleate + Phenylephrine is CONTRAINDICATED in children under 4 years
- Advised clinicians to suspect AKI due to DEG when children present with vomiting/oliguria after recent syrup use and to report suspected cases to nearest Drug control / Pharmacovigilance authorities immediately.

C. CDSCO & IPC Mandates:

NSQ and Spurious Drug Alert: The Central Drugs Standard Control Organisation (CDSCO) issued "Not of Standard Quality" (NSQ) and Spurious Drug alerts for the specific batches of Coldrif, Respifresh TR ,and ReLife products. It also initiated a nationwide recall of the implicated batches with safety announcements.

IPC Amendment List-09 (IP 2022): The Indian Pharmacopoeia Commission now mandates that all the raw materials of Propylene Glycol and Glycerine must undergo specific testing for DEG and Ethylene Glycol (EG). The limit is strictly capped at NMT 0.10%.

FDC Contraindication: The CDSCO reiterated warnings regarding the Fixed-Dose Combination of *Chlorpheniramine Maleate + Phenylephrine* and manufacturers must label these as contraindicated in children below 4 years of age.

D. WHO Announcement:

The World Health Organization also issued a global alert which identified the products *Coldrif*, *Respifresh-TR*, and *ReLife* as substandard and toxic products confirmed to contain the toxin Diethylene Glycol (DEG). The statement urged international regulators to increase surveillance in order prevent the cross border circulation of these batches and explicitly categorized them as a fatal risk to infants and young children.

Historical Context: Similar Tragedies Of Past

The way forward: Learnings from cough syrup tragedies

1) Zero tolerance in quality testing – No blind trust in vendors: In the Coldrif tragedy , the manufacturers relied on CoA certification from vendor documentation rather than independent verification – thus quality control was bypassed. Strictly following the IPC Amendment List-09 which mandates 100% in house testing of every solvent container for contaminants like DEG must be followed by every manufacturer rather than having blind trust in vendor certification.

2) Proactive Pharmacovigilance practices

Future safety strategies can integrate clinical findings with regulatory action by enhancing pharmacovigilance systems to trigger proactive immediate investigations whenever "sentinel clusters" of unexplained paediatric renal failure are reported by hospitals thereby reducing response time.

3) Stringent Clinical Stewardship and avoidance of irrational FDCs

Cough syrup tragedies like Coldrif tragedy highlighted the lethal risk of prescribing complex Fixed-Dose Combinations (FDCs) to paediatric age group for self-limiting viral coughs, exposing a physiologically vulnerable population to avoidable chemical hazards. The regulatory body alerts and announcements on usage of cough syrups in paediatric age groups including the avoidance in age group under 2 years , contraindication of certain FDCs such as Chlorpheniramine Maleate + Phenylephrine under 4 years and discouragement of over the counter purchase of cough syrups must be disseminated across healthcare professionals and consumers to promote increased paediatric patient safety. Professional medical associations must drive clinical stewardship to stop the reflex prescription of these high-risk formulations for children.

4) Data Integrity & The Digital Shift (Schedule M)

This tragedy also revealed how manual record keeping allowed for the potential retrospective fabrication of quality checks which made it difficult to audit whether testing actually occurred or was merely documented. The implementation of Revised Schedule M is hence essential to eliminate data manipulation. The manufacturers must transition to computerized systems with unalterable audit trails thereby ensuring that all laboratory results are authentic, traceable, and ultimately immune to tampering.

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ORPHAN DRUGS & RARE DISEASES - PHARMACOVIGILANCE (PV) CHALLENGES

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Introduction

Pharmacovigilance for orphan drugs and rare diseases presents unique and critical challenges due to small patient populations, limited clinical data, diagnostic complexity, and the urgent need for post-marketing safety monitoring. Orphan drugs are designed for the treatment of rare disease conditions with very low prevalence making them critical for patients with otherwise unmet medical needs. Because patient populations are small and often heterogeneous, traditional pharmacovigilance (PV) methods face unique limitations and ethical considerations.

Pharmacovigilance Challenges

Sparse Data and Limited Clinical Experience

- Clinical trials for orphan drugs typically enroll very few patients, thus long-term safety data are scarce at approval.
- Small populations reduce the statistical power to detect infrequent or delayed adverse drug reactions (ADRs), which may only be identified after widespread clinical use.
- Spontaneous reporting systems are less effective since healthcare providers may lack experience both with the disease and its treatments, leading to underreporting of ADRs.

Diagnostic Delay and Clinical Variability

- Many rare diseases are under diagnosed or misdiagnosed, delaying recognition of ADRs and complicating the association between drug safety signals and outcomes.
- Clinical variability in disease manifestation makes it difficult to distinguish between drug-related events and the natural course of disease.

Off-Label and Early Access Use

- Orphan drugs are sometimes used off-label or in special access programs before full approval, with limited ongoing monitoring.
- This can introduce unique safety signals not observed in abbreviated pre-approval studies.

Regulatory and Methodological Hurdles

- Regulations differ among countries, and expertise in rare disease pharmacovigilance is still maturing in many regulatory agencies.
- Agencies such as USFDA, EMA, CDSCO (India), ANVISA (Brazil), and SFDA (Saudi Arabia) offer incentives and special frameworks but require ongoing post-marketing safety evaluation.

Approaches to Strengthening Pharmacovigilance

Post-Marketing Surveillance and Risk Management

- Real-world data (RWD) integration—using patient registries, electronic health records, and digital platforms—expands the ability to detect rare events and long-term outcomes.
- Disease registries and patient advocacy networks help in signal detection and reporting, compensating for the lack of large datasets.

Global and Interdisciplinary Collaboration

- Collaboration with regulatory authorities, patient groups, and international pharmacovigilance networks aggregates scarce data, strengthening ADR detection globally.
- Periodic interdisciplinary reviews with clinical, regulatory, and statistical experts are recommended for focused signal detection in rare disease cohorts.

Qualitative Signal Detection and Literature Monitoring

- Structured, qualitative signal detection methods enhance the ability to uncover subtle safety signals in small datasets.
- Systematic monitoring of scientific literature and local publications is essential to capture new safety information emerging from real-world and off-label use cases.

Continued Patient and Provider Engagement

- Initiatives to raise awareness among clinicians, patients, and caregivers about the need to report adverse events are essential for PV in rare diseases.
- Patient involvement in pharmacovigilance, such as self-reporting platforms and qualitative feedback, adds granularity to safety profiles.

Regulatory References and Frameworks

- The US Orphan Drug Act provides a pathway for orphan drug designation and post-marketing commitments, including pharmacovigilance.
- The European Medicines Agency (EMA) enforces centralized procedures for orphan drug approval and mandates post-authorization safety studies.
- India's CDSCO and SFDA in Saudi Arabia require robust justification of disease rarity, safety, and ongoing monitoring commitments for orphan drug approval.
- Real-world evidence requirements and pharmacovigilance plans (including risk minimization and signal management strategies) are now standard parts of regulatory submissions.

Case Studies Illustrating PV Challenges

- The Saudi Food and Drug Authority’s systematic review of 35 orphan drugs demonstrated the need for extensive safety signal analysis despite limited reports, resulting in updated labels, signal evaluations, and monitoring continuation.
- Pulmonary hypertension drug bosentan safety was closely monitored through a disease-specific registry, highlighting the value of real-world surveillance.
- Immune checkpoint inhibitor pembrolizumab, used for rare Merkel cell carcinoma, required tailored immune-related adverse event monitoring.
- Olaparib for BRCA-mutated ovarian cancer underscored the role of genetic stratification in PV

Table 1 : Challenges Vs Innovative solutions

Challenges	Innovative solutions
Small clinical trial populations	Use Real-world data (RWD) ,patient registries, and digital platforms
Underreporting & lack of awareness	Patient and provider education; direct patient reporting |
Traditional statistical limitations	Qualitative signal detection; AI/ML analytics
Regulatory variability and delays	Global collaboration; adaptive trial designs
Off-label and early access use	Continuous safety monitoring; local literature surveillance|

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PHENOCONVERSION- THE DRUG-DRUG-GENE CONVERSION

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Phenoconversion refers to the discordance between an individual's genetically predicted drug metabolizer status and their actual, observed metabolizing capacity due to non-genetic influences. Although pharmacogenetic genotyping can classify patients into predicted CYP450 phenotypes such as normal, intermediate, poor, rapid or ultrarapid metabolizers, this classification assumes stable enzyme function[1]. In clinical practice, cytochrome P450 activity is dynamic and modifiable, and therefore an individual who is genotypically a normal metabolizer may be functionally converted. to a poor metabolizer under certain circumstances. This mismatch alters pharmacokinetics, therapeutic response, and increases risk of adverse effects.

Phenoconversion importance in clinical practice:

1. Phenoconversion is most frequently ascribed for cytochrome P450 enzymes, especially CYP2D6 and CYP2C19, but has also been documented for CYP2C9, CYP3A4 and CYP3A5. The mismatch occurs when environmental, pathological, or therapeutic factors suppress or enhance enzyme function. This has major implications for dose prediction, clinical outcomes, and interpretation of pharmacogenomic studies.
2. Co-medication plays a central role in producing phenoconversion. Potent CYP450 inhibitors, such as paroxetine, fluoxetine, quinidine, fluconazole, fluvoxamine, and bupropion, can reduce metabolic capacity to an extent equivalent to genetic loss-of-function[2].
    a. For Example: Fluoxetine markedly increases exposure to CYP2D6 substrates, and quinidine can convert nearly all CYP2D6 extensive metabolizers to a poor metabolizer phenotype.
    b. Conversely, enzyme inducers such as rifampicin, carbamazepine, phenytoin, and chronic smoking can increase metabolic clearance, particularly through CYP1A2 and CYP3A enzymes.
    c. Over-the-counter agents (e.g., cimetidine, omeprazole) and herbal supplements are further under-recognized contributors.
3. Patient-related factors substantially contribute to phenoconversion. Advanced age, systemic inflammation, malignancy, liver disease, alcohol use, pregnancy, and vitamin D status have all been associated with reduced CYP450 activity. Inflammatory cytokines suppress transcription and expression of CYP enzymes, leading to reduced clearance of susceptible drugs. Clinical studies in cancer patients demonstrate that a substantial proportion of individuals who are genetically normal CYP2C19 metabolizers phenotypically behave as poor metabolizers. Similar findings have been reported in chronic liver disease and infectious states.
   Ex: 1. Cytokine-mediated down-regulation in hepatic diseases increases the Tacrolimus toxicity.
   2. Cancer suppresses CYP2C19. Leading to higher exposure to Proton pump inhibitors.

Clinical consequences of phenoconversion:

- Phenoconversion can **precipitate therapeutic failure** when activation of prodrugs is impaired, as with codeine requiring CYP2D6-mediated formation of morphine.
- Conversely, phenoconversion may **lead to toxicity** when clearance of active drugs decreases, particularly for agents with narrow therapeutic windows. For example, co-administration of CYP2C19 inhibitors with warfarin increases bleeding events by reducing S-warfarin clearance. Such consequences highlight that present-time phenotype, rather than stable genotype, determines drug response[3].

Cytochrome inhibitors:

Drug / Class	Mechanism	Affected CYP Enzyme(s)	Phenoconversion Effect	Clinical consequence
Paroxetine, Fluoxetine, Quinidine.	Potent inhibitor	CYP2D6	EM → PM	Therapeutic failure of analgesics
Fluvoxamine	Potent inhibitor	CYP1A2, CYP2C19	EM → PM	Decreases the conversion of pro-drugs
Cimetidine	Inhibitor	Multiple CYPs	EM → PM	↓ clopidogrel activation (treatment failure risk)
Ritonavir	Potent inhibitor	CYP3A4, CYP2D6	EM → PM	Increases toxicities (sedation, bradycardia, bleeding)
Omeprazole	Inhibitor	CYP2C19	EM → PM	Increases the risk of bleeding with Warfarin

Note: PM-Poor Metabolizer, EM- Extensive Metabolizer

Cytochrome inducers:

Drug / Class	Mechanism	Affected CYP Enzyme(s)	Phenoconversion Effect	Clinical consequence
Rifampicin	Strong inducer	CYP3A4, CYP2C19, CYP2C9	PM → IM or EM	Sub-therapeutic response
Carbamazepine	Inducer	CYP3A4, CYP2C19	PM → EM	Treatment failure when given with clobazam, tacrolimus[4]
Phenytoin	Inducer	CYP3A4, CYP2C19	PM → EM	Breakthrough seizures due to loss of antiepileptic effect of co-medications

Note: PM-Poor Metabolizer, EM- Extensive Metabolizer

From a research perspective, phenoconversion challenges the interpretation of genotype-outcome association studies. Most studies assume that genotype alone determines clinical phenotype, yet a substantial fraction of genotypic normal metabolizers may phenotypically function as poor metabolizers. This genotype–phenotype mismatch can weaken observed associations, lead to conflicting study outcomes, and impair reproducibility[5]. Consequently, the predictive capacity of pharmacogenetic analysis may be overestimated if phenoconversion is unaccounted for.

Conclusion:

Future directions require incorporation of dynamic phenotype information into personalized therapy models. Proposed strategies include periodic or situational substrate-based phenotyping, therapeutic drug monitoring, and clinical decision systems that adjust predicted phenotypes based on current medications and disease states. Integrating genotypic data with environmental and physiological modifiers represents a necessary evolution towards a more accurate and functional model of personalized pharmacotherapy. Recognition and management of phenoconversion are therefore essential steps in advancing precision medicine.

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VIGILANCE FOR IN VITRO DIAGNOSTIC DEVICES

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In vitro diagnostic (IVD) devices play a vital role in modern healthcare — from routine blood tests to complex genetic analyses — providing critical information for diagnosis, monitoring, and treatment decisions. Ensuring their safety, reliability, and performance throughout their lifecycle is essential for maintaining trust in medical diagnostics.

What is IVD Vigilance?

Vigilance for in vitro diagnostic device refers to the systematic monitoring, evaluation, and reporting of adverse events, malfunctions, or performance issues associated with IVDs after they are placed on the market. The goal is early detection of potential risks, trend analysis, and implementation of corrective actions to protect patients, users, and public health.

Types of Reportable Incidents

Events that may trigger vigilance reporting include:

- False-positive or false-negative test results leading to inappropriate patient management
- Device malfunction or failure during testing
- Labeling errors or misleading instructions
- Software or calibration issues affecting accuracy
- User injuries or biohazard exposure during testing

Regulatory Framework

Under global regulations — such as the Medical Device Rules (MDR), 2017 in India and the EU In Vitro Diagnostic Regulation (IVDR) 2017/746 — manufacturers, importers, and healthcare institutions are required to establish vigilance systems. These include mechanisms for adverse event reporting, trend analysis, field safety corrective actions (FSCAs), and periodic summary submissions to regulatory authorities. In India, the Materiovigilance Programme of India (MvPI), coordinated by the Indian Pharmacopoeia Commission (IPC), has extended its scope to include IVDs. Laboratories and diagnostic centers are encouraged to report device-related issues through Device Adverse Event (DAE) reporting forms or the MvPI portal.

Why Vigilance Matters

Robust vigilance ensures that even minor performance deviations are captured and corrected before they escalate into public health concerns. Continuous feedback from end users helps manufacturers enhance product design, strengthen quality systems, and prevent recurrence of similar events.

The Way Forward

Promoting a culture of vigilance among laboratory professionals is essential. Training on recognizing and reporting IVD-related incidents, establishing institutional vigilance committees, and integrating feedback loops with manufacturers are key steps.

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CHALLENGES AND OPPORTUNITIES IN MATERIOVIGILANCE IMPLEMENTATION

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Materiovigilance implementation faces challenges like underreporting and lack of awareness among healthcare professionals, while new opportunities arise from AI integration and enhanced regulatory collaboration.

Challenges in Materiovigilance Implementation:

1. Underreporting and Lack of Awareness:

A significant gap exists between observing adverse events and actually reporting them. Many healthcare professionals and patients are unaware of existing programs like the Materiovigilance Programme of India (MvPI), or the specific procedures for reporting.

2. **Fear of Reprisal:**

Healthcare professionals often fear that reporting adverse events could lead to legal liabilities or professional repercussions, which discourages transparency and open communication.

3.**Inadequate Training and Education:**

Materiovigilance training is often not integrated into standard academic curricula for medical and paramedical courses, leading to a lack of foundational knowledge and skills in adverse event reporting.

4.**Time and Resource Constraints:**

Busy clinical schedules and resource-constrained settings leave little time for the administrative tasks associated with reporting adverse events.

5.**Data Quality and Infrastructure Issues:**

There are challenges related to poor data quality, the absence of streamlined digital reporting tools, and a lack of publicly accessible, centralized databases in some regions, which hampers effective data analysis and signal detection.

Opportunities in Implementation

- **Enhanced Patient Safety:** The primary opportunity is the potential to significantly improve patient safety by systematically monitoring devices, identifying patterns of failure, and implementing corrective measures and design modifications.
- **Integration of Advanced Technologies:** The use of artificial intelligence (AI) and machine learning (ML) can revolutionize materiovigilance by facilitating real-time data analysis, early signal detection, and the processing of large, unstructured datasets from sources like electronic health records and social media.
- **Improved Regulatory Compliance and Decision-Making:** A strong materiovigilance system provides evidence-based data that supports regulatory bodies, such as the CDSCO and FDA, in making informed decisions, developing new laws, and issuing safety alerts faster.

- **Collaboration and Information Exchange:** Opportunities exist for increased collaboration among engineers, regulators, healthcare practitioners, and technology companies to improve data management, analysis, and information sharing both nationally and internationally.
- **Standardization and Harmonization:** Efforts towards global harmonization of reporting guidelines and regulatory frameworks can reduce discrepancies and create a more efficient, unified system for medical device safety across different countries.
- **Empowering Stakeholders:** Raising awareness and providing accessible, user-friendly digital reporting platforms can empower healthcare professionals and patients to actively participate in the monitoring process, fostering a culture of safety.

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PSYCHOTROPIC POLYPHARMACY INDUCED QT PROLONGATION WITH PROARRHYTHMIC RISK IN AN ELDERLY PATIENT : A CASE REPORT

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Dr. Akilandeeshwari
Final Year PG

Drug-induced QT prolongation continues to be a major safety concern in pharmacovigilance, particularly among elderly patients who live with multiple comorbidities and are often exposed to complex medication regimens. This is an interesting case where a 72-year-old elderly male presented to the psychiatric outpatient department on 06/10/2025, accompanied by family members, with complaints of increased and excessive talking, intermittent irrelevant speech, irritability, and progressive memory impairment over the past one year. These symptoms had worsened significantly during the preceding one week, leading to considerable difficulty in home-based care and prompting hospital evaluation.

The patient was a known case of dementia with psychotic features for the past two years, with multiple comorbidities including Parkinson's disease, type 2 diabetes mellitus, hypertension, and coronary artery disease. He also had a history of slip and fall in 2024, for which he underwent proximal femur reconstruction surgery.

The patient was receiving multiple long-term medications which includes T.Quetiapine, T.Syndopa Plus (Levodopa + Carbidopa), T.Clopitorva (Clopidogrel + Atorvastatin), T.Metformin, T.Glyburide, T.Shelcal (Calcium + Vitamin D_3) and B-complex supplements.

On general examination, the patient was afebrile, with a heart rate of 80 beats per minute, respiratory rate of 24 cycles per minute, and blood pressure of 130/80 mmHg. There was no evidence of pallor, icterus, cyanosis, clubbing, lymphadenopathy, or pedal edema. Neurological examination revealed that the patient was oriented, with reduced psychomotor agitation. His speech was relevant but slurred, affect was reactive, and there were no abnormalities in thought content or perception at the time of evaluation. Examination of other systems, including cardiovascular, respiratory, and gastrointestinal systems, was unremarkable.

Baseline investigations on the day of admission revealed Hemoglobin: 11.4 g/dL and HbA1c: 8.8%, Liver function tests, renal function tests, and lipid profile were within normal limits. An electrocardiogram (ECG) performed on the day of admission, revealed significant QT prolongation, with a corrected QT interval (QTc) of 514 ms.

In view of the prolonged QTc, Quetiapine was discontinued on the day of admission, and Pimavanserin was initiated as an alternative for managing psychotic symptoms associated with Parkinson's disease. Additionally, the patient was started on T.Memantine, T.Alfuzosin, T.Bethanechol, Probiotic capsule (Bifilac) and Oral rehydration solution On Day 3 of hospitalization further medications were added, that includes T.Lorazepam, T.Melatonin, T.Propranolol, T.Amlodipine, T.Mirtazapine A repeat ECG performed on Day 4 (10/10/2025) showed a QTc of 491 ms, indicating partial improvement, though the QT interval remained prolonged.

Prescription Audit and Risk Assessment – STOPP / START criteria , Beers Law A detailed prescription audit identified concurrent use of multiple QT-prolonging medications, including Quetiapine, Pimavanserin, Mirtazapine, Propranolol, and Alfuzosin. The patient was also exposed to an increased anticholinergic burden, particularly due to the combination of Bethanechol and Mirtazapine, which may adversely affect cognition and autonomic function in the elderly.

Several medications were found to be potentially inappropriate according to STOPP/Beers criteria, notably-

Violation in STOPP criteria	Reason to be considered in elderly patients
Sulphonylurea	Risk of prolonged Hypoglycemia
Propranolol	Risk of suppressing hypoglycemic symptoms
Lorazepam	Confusion, Impaired balance, falls, RTA

The START criteria emphasize appropriate treatment and monitoring. In this case, they support the need for regular ECG monitoring, careful drug selection with lower QT-prolonging potential, and close surveillance in elderly patients with Parkinson's disease and cardiovascular comorbidities The overlapping use of Quetiapine and Pimavanserin was particularly significant. Both agents are known to block cardiac hERG (IKr) potassium channels, leading to delayed ventricular repolarization and QTc prolongation. While Quetiapine demonstrates a dose-dependent QT effect, Pimavanserin typically causes a modest QTc increase of approximately 5–8 ms. However, in the presence of advanced age, polypharmacy, cardiovascular disease, Parkinson's-related autonomic dysfunction, and possible pharmacokinetic interactions, the cumulative effect becomes clinically relevant.

Clinical Implications

The patient's overall risk was amplified by advanced age, multiple comorbidities, polypharmacy, overlapping psychotropic use, and anticholinergic load. In individuals with Parkinsonism, a QTc exceeding 500 ms is associated with a markedly increased risk of torsades de pointes, a potentially life-threatening ventricular arrhythmia.

Evidence suggests that QT prolongation occurs in approximately 1–10% of patients receiving antipsychotics, while clinical trials of Pimavanserin report QTc values ≥500 ms in 0.3–0.5% of treated individuals. Although torsades de pointes remains relatively uncommon, the risk escalates significantly when multiple QT-prolonging drugs are co-administered.

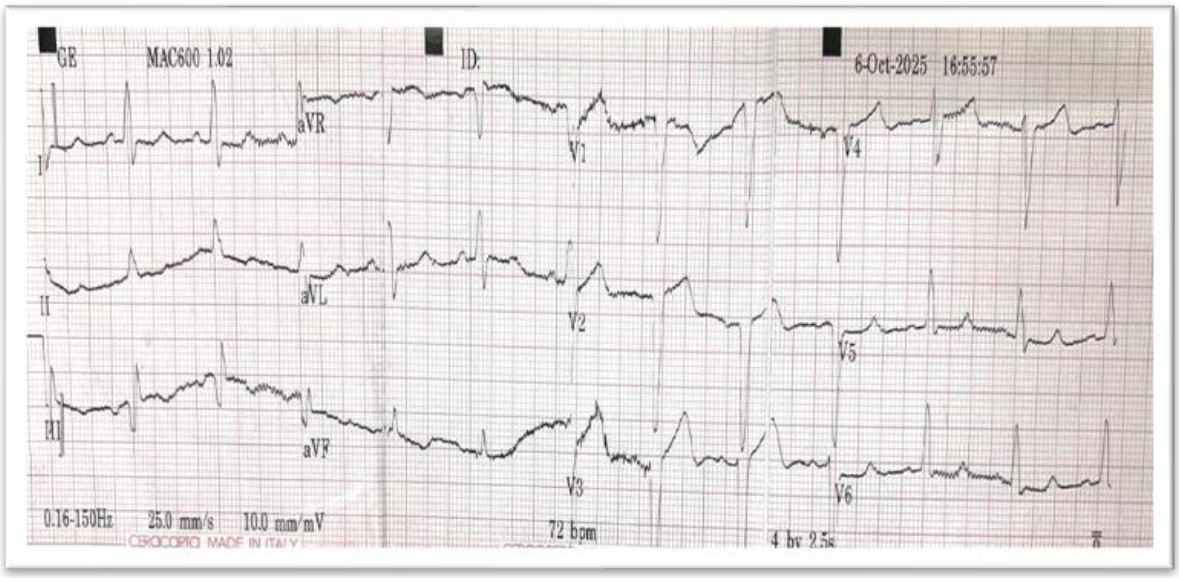
Overall, routine use of STOPP/START and Beers criteria, along with regular prescription review and pharmacovigilance reporting, can help reduce polypharmacy-related harm and improve safety in geriatric patients

Conclusion

This case underscores the critical importance of regular and structured medication review in geriatric patients, particularly those with neurological disorders and cardiovascular comorbidities. Routine assessment using tools for identifying potentially inappropriate medications, vigilant monitoring of QT intervals, evaluation of anticholinergic burden, and careful consideration of drug–drug interactions are essential to prevent avoidable cardiac complications.

Furthermore, timely reporting of QT-related adverse drug reactions to the Pharmacovigilance or ADR Monitoring Unit is vital. Such reporting facilitates early signal detection, supports system-level safety improvements, and ultimately strengthens patient care and medication safety within healthcare institutions.

ECG OF THE PATIENT SHOWING QT - PROLONGATION



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NEW DRUGS APPROVED BY FDA – 2025

Dr Karunika S
Junior Pharmacovigilance Associate

SI.No	Date of Notification	Drugs	Indication
1	2nd July, 2025	linvoseltamab-gcpt [Lynozyfic]	To treat relapsed or refractory multiple myeloma after at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody
2	2nd July, 2025	Sunvozertinib [Zegfrovy]	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, with disease progression on or after platinum-based chemotherapy
3	3rd July, 2025	Sebetralstat [Ekterly]	To treat acute attacks of hereditary angioedema
4	23rd July, 2025	Delgocitinib [Anzupgo]	To treat moderate-to-severe chronic hand eczema when topical corticosteroids are not advisable or produce an inadequate response
5	28th July, 2025	Sepiapterin [Sephience]	To treat hyperphenylalaninemia in patients with sepiapterin-responsive phenylketonuria, in conjunction with a phenylalanine-restricted diet
6	31st July, 2025	Aceclidine [Vizz]	To treat presbyopia
7	06th August, 2025	Dordaviprone [Modeyso]	To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy
8	08th August, 2025	Zongertinib [Hernexeos]	To treat adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy
9	12th August, 2025	Brensocatib [Brinsupri]	To treat non-cystic fibrosis bronchiectasis
10	21st August, 2025	Donidalorsen [Dawnzera]	To prevent attacks of hereditary angioedema
11	29th August, 2025	Rilzabrutinib [Wayrilz]	To treat persistent or chronic immune thrombocytopenia that has not sufficiently responded to immunoglobulins, anti-D therapy, or corticosteroids

12	19th September, 2025	Pembrolizumab [Keytruda] and Berahyaluronidase alfa-pmph [Qlex]	To treat adult and pediatric (12 years and older) solid tumor indications approved for the intravenous formulation of pembrolizumab
13	19th September, 2025	Elamipretide [Forzinity]	To improve muscle strength in patients with Barth syndrome weighing at least 30 kg
14	25th September, 2025	Imlunestrant [Inluriyo]	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, estrogen receptor-1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
15	25th September, 2025	Paltusotine [Palsonify]	To treat acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option
16	30th September, 2025	Remibrutinib [Rhapsido]	To treat chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamine treatment
17	7th October, 2025	Nerandomilast [Jascayd]	To treat idiopathic pulmonary fibrosis
18	24th October, 2025	Elinzanetant [Lynkuet]	To treat moderate-to-severe vasomotor symptoms due to menopause
19	03rd November, 2025	Doxecitine and Doxribtimine [Kygevvi]	To treat thymidine kinase 2 deficiency in patients who start to show symptoms when they are 12 years old or younger
20	13th November, 2025	Ziftomenib [Komzifti]	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation who have no satisfactory alternative treatment options
21	18th November, 2025	Plozasiran [Redemplo]	To reduce triglycerides in adults with familial chylomicronemia syndrome
22	19th November, 2025	Sevabertinib [Hyrnuo]	To treat locally advanced or metastatic non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations in patients who received a systemic therapy
23	25th November, 2025	Sibeprenlimab-szsi [Voyxact]	To reduce proteinuria in primary immunoglobulin A nephropathy in adults at risk for disease progression

Reference:

https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2025

DRUGS SAFETY UPDATES - PVPI – JULY – DECEMBER 2025

SI. No.	Date of Notification	Suspected Drug	Indication	Adverse Drug Reaction
1	29th August 2025	Tranexamic Acid	• For the treatment of abnormal bleeding in which local hyperfibrinolysis is considered to be involved (pulmonary, haemorrhage, epistaxis, renal bleeding abnormal bleeding during or after prostate surgery). • Haemorrhage or risk of haemorrhage in increased fibrinolysis of hereditary angioneurotic oedema. • For the treatment of excessive bleeding in patients with hemophilia during & following tooth extraction. • For the treatment of menorrhagia. • For the prevention of oral hemorrhage in anticoagulant treated patients undergoing oral surgery.	Nasal Congestion
2	29th August 2025	Metoclopramide	• To restore normal coordination and tone the upper digestive tract and relieve symptoms of gastro-duodenal dysfunction including heart burn, dyspepsia, nausea and vomiting associated with such conditions as reflux oesophagitis, gastritis, duodenitis and hiatus hernia. • For the treatment of nausea and vomiting.	Tachycardia
3	26th September 2025	Erythromycin	• Alternative to penicillin in hypersensitive patients; pneumonia; Legionnaires' diseases; syphilis; chancroid; chlamydia; non-gonococcal urethritis; prostatitis; lymphogranuloma venereum; Campylobacter enteritis; relapsing fever; diphtheria and whooping cough prophylaxis upper respiratory tract infection, acne vulgaris, psychosis, vulgaris.	Fixed Drug Eruption

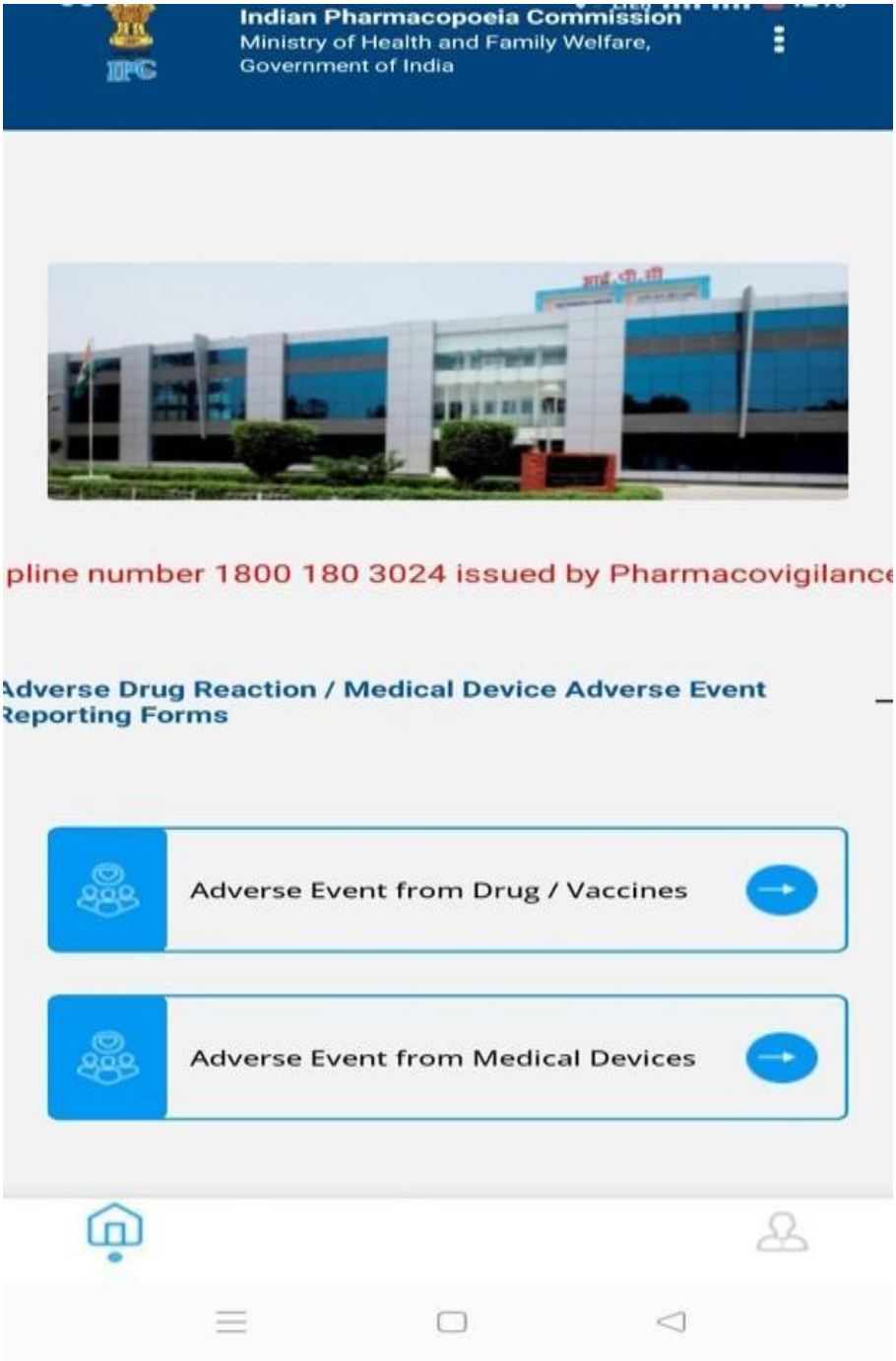
Reference:

https://www.ipc.gov.in/mandates/pvpi/pvpi-outcome.html?id=1361:drug-alerts-2025&catid=2

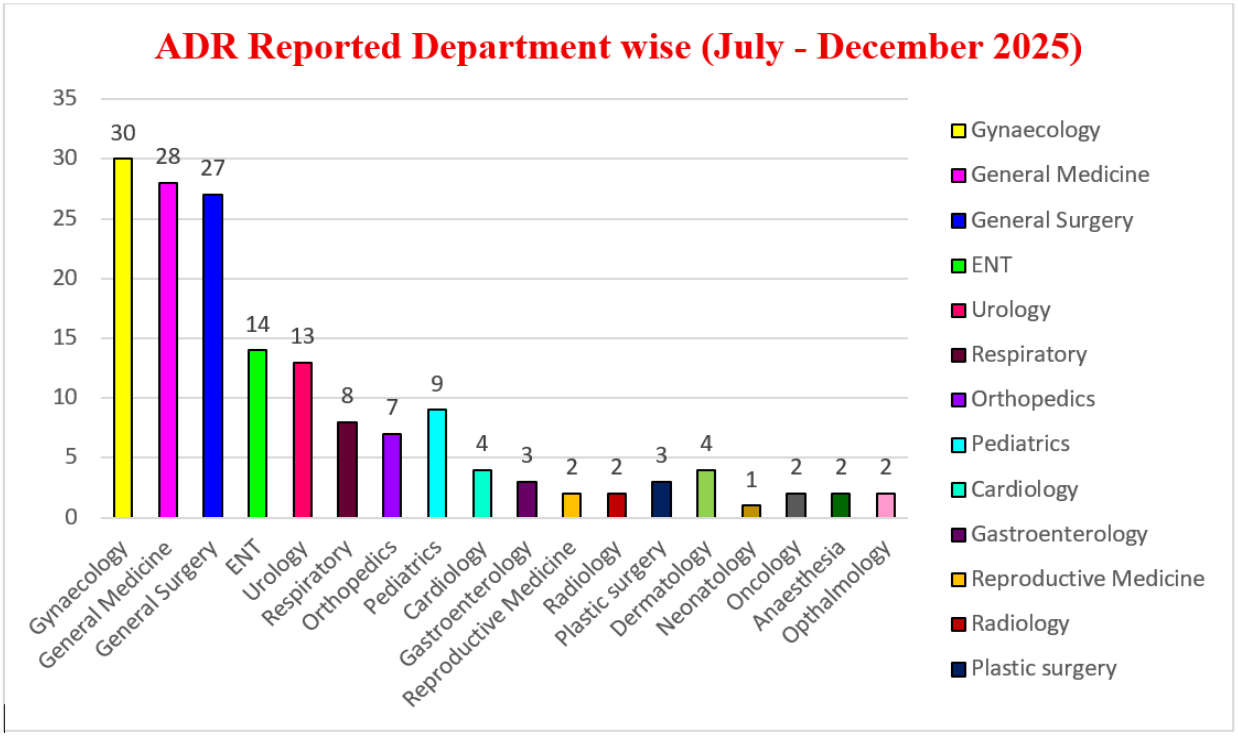
RECENT PVPI UPDATES-2025 (JULY-DECEMBER)

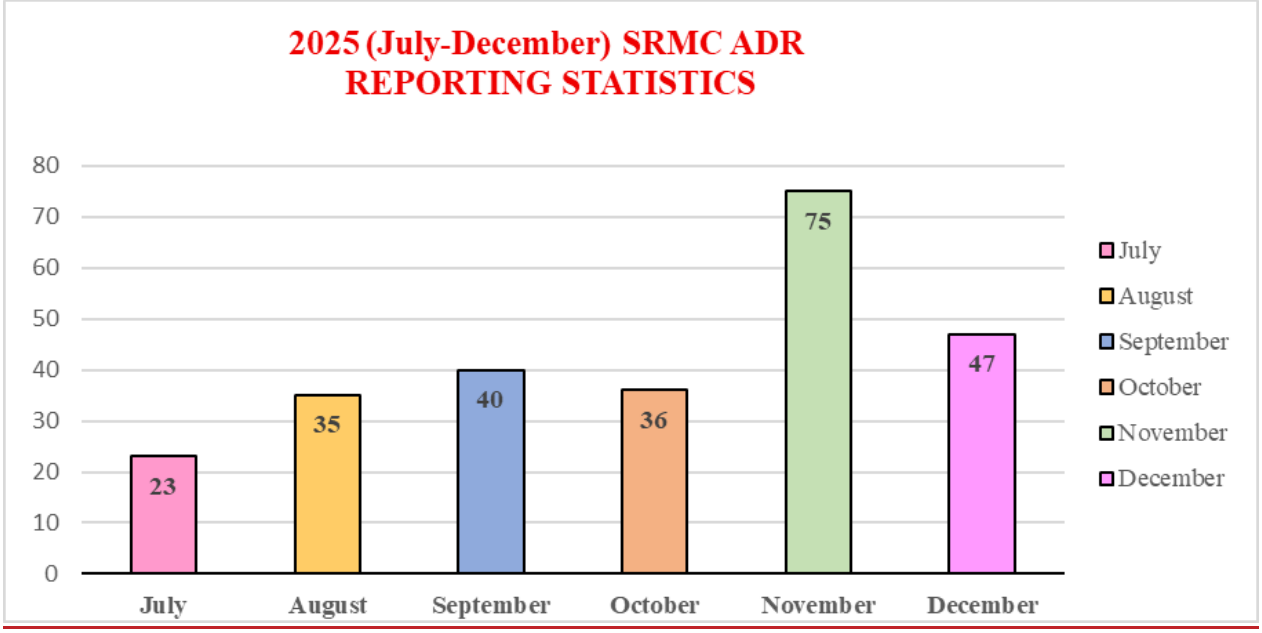
ADR PvPI mobile application – ADR PvPI 2.0 is now live and available for download on the Google Play store. This enhanced version of the application aims to further strengthen our pharmacovigilance initiatives by providing a simplified and accessible platform for users to report adverse drug reactions (ADRs) and medical device-related adverse events directly from their smartphones.

Download ADR PvPI 2.0:
https://play.google.com/store/search?q=adr+pvpi+2.0&c=apps&hl=en_IN



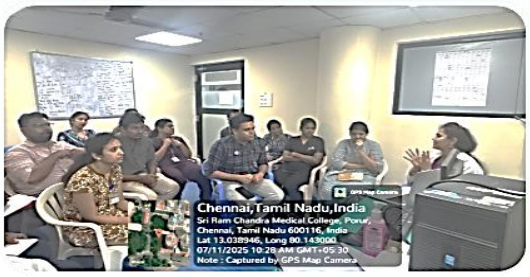
SPOTLIGHT
2025(JULY - DECEMBER) – SRMC - ADR-REPORTING STATISTICS





DEPARTMENTAL HAPPENINGS
PV SENSITIZATION PROGRAMMES

S. No	Date of Training	Title of the Training	Department	No. of. Participants
1	11.07.2025	Pharmacovigilance and Materiovigilance	Neonatology	30
2	31.07.2025	Boosting Public Confidence in ADR Reporting	Public	50
3	13.08.2025	Pharmacovigilance and Materiovigilance	Medication Safety Team	50
4	19.08.2025	Boosting Public Confidence in ADR Reporting	Public	30
5	18.09.2025	Boosting Public Confidence in ADR Reporting	Public	50
6	19.09.2025	Boosting Public Confidence in ADR Reporting	Public	40
7	07.10.2025	Pharmacovigilance and Materiovigilance	Pharmacists	40
8	23.10.2025	Boosting Public Confidence in ADR Reporting	Public	30
9	23.10.2025	Pharmacovigilance, Materiovigilance and recent cough syrup issue	Paediatrics	25
10	03.11.2025	Pharmacovigilance and Materiovigilance	Orthopedics	30
11	13.11.2025	Boosting Public Confidence in ADR Reporting	Public	30
12	15.11.2025	Pharmacovigilance and Materiovigilance	Other ADR reporting hospitals of SRMC-AMC	110
13	14.11.2025	Boosting Public Confidence in ADR Reporting	Public	30
14	19.12.2025	Pharmacovigilance and Materiovigilance	Ward Staff Nurses and ICU Staff Nurses	100



Pharmacovigilance Sensitization Programme - Neonatology Department - 11.07.2025

Pharmacovigilance Public Awareness - Pamphlet Distribution - 31.07.2025

Pharmacovigilance Sensitization Programme - Medication Safety Team - 13.08.2025

Pharmacovigilance Sensitization Pharmacists- 07.10.2025

Pharmacovigilance Sensitization Programme - Cough Syrup Alert – Pediatrics Department – 23.10.2025

NATIONAL PHARMACOVIGILANCE WEEK CELEBRATION -2025
SEPTEMBER 17-23,2025

Walkathon for Public awareness on PV & MV

We have conducted a walkathon on 17.09.2025 in view of National Pharmacovigilance Week Celebration 2025 to create awareness among public and health care professionals about pharmacovigilance. The Respected Vice Chancellor and Dean Medical College of SRMC & RI flagged off the Walkathon rally. Associate deans, Medical Superintendent, Medical director, Pharmacovigilance committee members, Doctors Postgraduates, Pharmacy students, Nursing students, Dental students, Paramedical students and M.Sc clinical research students participated in walkathon. The event started from medical college to Medical centre block and G-block to sensitize the health care professionals and patients. The pamphlets were printed in Tamil [Regional] and English languages were distributed to health care professional and general public to increase the awareness of pharmacovigilance. Nearly 100-200 pamphlets are distributed to the public. We also explained about the importance of ADR reporting.

Public Awareness Program

A sensitization program was held at the Urban Health Centre, Thiruvanmiyur on 18th September 2025 and Rural Health Centre on 19th September 2025 to raise awareness about the importance of reporting Adverse Drug Reactions (ADRs).The target audience included patients and healthcare professionals present at the centre. Faculties, postgraduates, Pharm D and M.Sc clinical research students were involved in the pharmacovigilance awareness activities in the Urban Health Centre, Thiruvanmiyur. The Doctor of Pharmacy internship students and M.Sc clinical research students done the role play [Nukkad Natak] to create awareness in pharmacovigilance and distributed awareness pamphlet in both tamil [Regional] and english language for general public, health care professionals.

Walkathon for Public awareness - NPW - 17.09.2025

Walkathon for Public awareness - NPW - 17.09.2025

Public Awareness Program - Urban Health Center, Thiruvanmiyur - 18.09.2025

Public Awareness Program - Rural Health Center, Vayalanallur- 19.09.2025

Quiz – PharmaVigil – IQ The ultimate drug safety challenge:

Quiz Competition – PharmaVigil – IQ The ultimate drug safety challenge was organized to create awareness and enhance knowledge on drug safety, adverse drug reaction (ADR) reporting, and the importance of pharmacovigilance among healthcare professionals and students. A prelims round was held on 15.09.2025 in which 19 teams (team of two participants) from various colleges across India participated, 5 teams were selected as finalists and the final round was conducted on 20.09.2025 at Department of Pharmacology, SRMC & RI. Prizes and certificates were distributed to the winners and participants.

Quiz-Pharmvigil-Finals
20.09.2025

Quiz-Pharmvigil-Finals
20.09.2025

MEDIVIGIL CME on 23.09.2025

CME ON "VIGILANCE ON MEDICAL DEVICES SAFETY" was organized and conducted by the Department of Pharmacology, SRMC & RI on 23.09.2025. Around 150 participants attended the program. We invited Prof. Dr. T. Aruna, MD, Co-ordinator – AMC, Professor and HOD, Dept. of Pharmacology, Govt. Kilpauk Medical College, Chennai, Tamilnadu as the chief guest of the event. The event was concluded with valedictory function distributing prizes to the winners of NPW 2025 events.

MEDIVIGIL CME - 23.09.2025

MEDIVIGIL CME - 23.09.2025

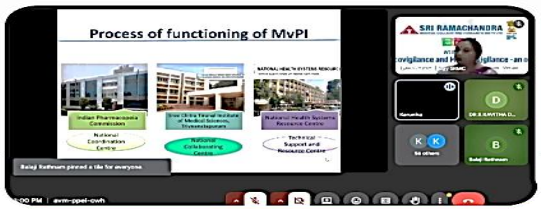
NPW 2025 - VALEDICTORY FUNCTION-23.09.2025

NPW 2025 - VALEDICTORY FUNCTION-23.09.2025

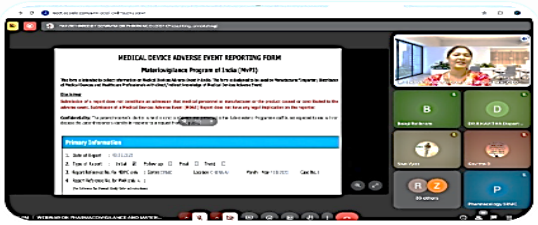
WEBINAR OF PHARMACOVIGILANCE & MATERIOVIGILANCE

The Department of Pharmacology, Sri Ramachandra Medical College and Research Institute (SRMC & RI), successfully organized a Webinar on "Pharmacovigilance and Materiovigilance – An Overview" on 15th November 2025, from 2:00 pm to 3:30 pm, through a virtual platform. The programme was conducted under the guidance of Dr. R. Kavitha, Professor & Head, Department of Pharmacology, and Co-ordinator, AMC–MDMC, SRMC & RI. The webinar aimed to enhance awareness on the significance of Adverse Drug Reaction (ADR) reporting, Medical Device Adverse Event (MDAE) reporting, and the overall functioning of Pharmacovigilance and Materiovigilance systems among healthcare professionals.

Webinar on Pharmacovigilance and Materiovigilance-Other ADR reporting hospitals of SRMC-AMC - 15.11.2025



Webinar on Pharmacovigilance and Materiovigilance-Other ADR reporting hospitals of SRMC-AMC - 15.11.2025



Webinar on Pharmacovigilance and Materiovigilance-Other ADR reporting hospitals of SRMC-AMC - 15.11.2025

Webinar on Pharmacovigilance and Materiovigilance-Other ADR reporting hospitals of SRMC-AMC - 15.11.2025

MATERIOVIGILANCE INTERNSHIP UPDATES – SRMC MDMC CENTRE

The Materiovigilance Programme at the Sri Ramachandra Medical College (SRMC) – Medical Devices Monitoring Centre (MDMC) continues to support academic training and capacity building for students interested in medical device safety and vigilance activities.

We are pleased to share that Ms. Rutuja Bhandare successfully completed her Materiovigilance internship at our SRMC-MDMC Centre during the period November 2025 to February 2026. During her internship, she actively participated in materiovigilance reporting activities, data collection, case documentation, and gained practical exposure to medical device safety monitoring and regulatory practices.

Further strengthening our academic and training initiatives, two new Materiovigilance internship students Mr.E. Senthil Kumar and Ms.A. Dharani have recently joined our SRMC-MDMC Centre to undergo their internship training for the period January 2026 to April 2026. They will be engaged in various materiovigilance activities, including adverse event reporting, data management, and awareness initiatives under the guidance of the MDMC team.

Ms . Rutuja Bhandare , MvPI intern completed her internship in SRMC-AMC-MDMC during the period November 2025 - January 2026

MOU – SANKARA NETHRALAYA

A Memorandum of Understanding (MoU) has been established between Sankara Nethralaya and SRMC AMC for the collection and validation of Adverse Drug Reaction (ADR) Reports which serves as a best practice in pharmacovigilance and for enhancing drug safety monitoring and reporting.

SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH

DETAILS OF MEMORANDUM OF UNDERSTANDING (MoU) / AGREEMENT

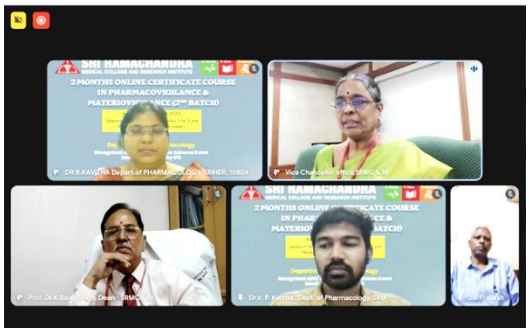
MoU/AGREEMENT PARTIES NAME	**SRIHER(DU) :** DEPARTMENT OF PHARMACOLOGY, SRI RAMACHANDRA MEDICAL COLLEGE & RESEARCH INSTITUTE, PORUR, CHENNAI-600116, TAMIL NADU **OTHER PARTY :** SANKARA NETHRALAYA R A PURAM, NEW NO.30, OLD NO.73, KAMARAJAR SALAI, R A PURAM, CHENNAI-600 028, TAMIL NADU
National / International	**National**
MoU/AGREEMENT Effective Date	**From** 20/12/2025 **To** 20/12/2028
Duration	**3 Year(s)**
Type of MoU/AGREEMENT	**Academic / Research / Service / Other** (i) Informational exchange between the collaborating institutions ☐ (ii) Learner exchange ☐ (iii) Faculty exchange ☐ (iv) Joint collaborative research projects ☐ (v) Twinning/Dual/Joint Degree programs ☐ (vi) Others ✓
New / Renewal	New
Scope	1. To receive the Adverse Drug Reaction data submitted by Sankara Nethralya a unit of Medical Research Foundation 2. To proceed for the validation and submission to Indian Pharmacopoeia Commission as per standard protocol 3. To periodically conduct Pharmacovigilance and Materiovigilance sensitisation for the healthcare professionals of Sankara Nethralaya 4. To enhance the patient safety by supporting the Pharmacovigilance programme of India and Materiovigilance programme of India.
Whether Financial Outflow Involved from SRIHER(DU)	**NIL**
Contact Person Details (Name/Designation/ Dept./ Phone No. /Mail ID)	DR.R.KAVITHA PROFESSOR & HEAD DEPARTMENT OF PHARMACOLOGY, SRI RAMACHANDRA MEDICAL COLLEGE & RESEARCH INSTITUTE, SRIHER,PORUR, CHENNAI-600116, TAMIL NADU 9444551410 hod.pharmacology@sriramachandra.edu.in
Signatory	**SRIHER(DU) :** Name:Dr.Uma Sekar Designation: Vice Chancellor SRIHER, PORUR, CHENNAI-600116, TAMIL NADU **OTHER PARTY :** Name:Dr.Girish Shiva Rao Designation: President & Executive Medical Director SANKARA NETHRALAYA R A PURAM, NEW NO.30, OLD NO.73, KAMARAJAR SALAI, R A PURAM, CHENNAI-600 028, TAMIL NADU

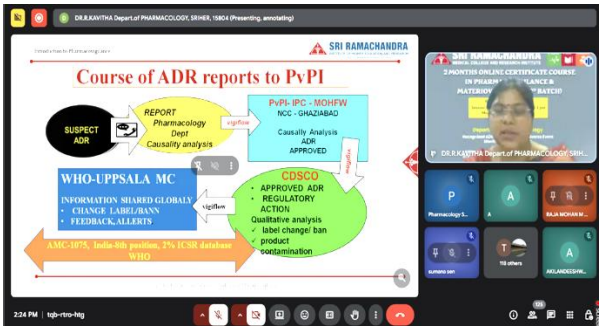
PROFESSOR AND HEAD
Department of Pharmacology
Sri Ramachandra Medical College

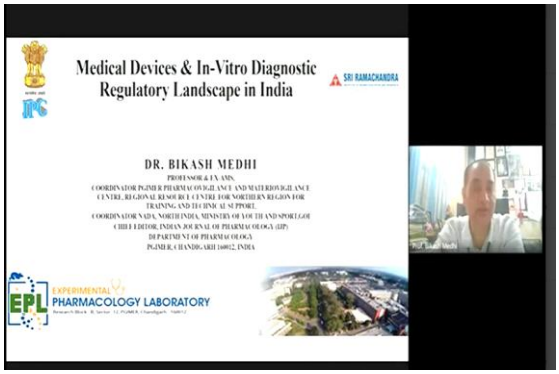
Signature of the HoD / Agreement Initiator

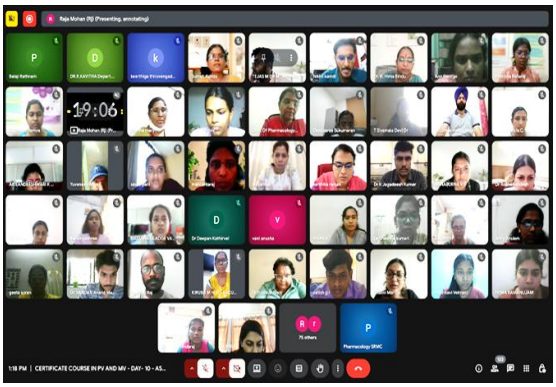
CERTIFICATE COURSE IN PHARMACOVIGILANCE & MATERIOVIGILANCE
August - October 2025

The Certificate Course in Pharmacovigilance and Materiovigilance (August–October 2025) was conducted as a value-added online programme by the Department of Pharmacology, SRMC & RI, SRIHER, Chennai. This was our second batch and it was delivered through live online interactive sessions and an integrated Learning Management System (LMS), developed in collaboration with Centre for Distance Online Education, SRIHER. The course comprised 16 structured modules combining theory with hands-on training in pharmacovigilance and materiovigilance practices. A total of **140 participants** from medical, dental, pharmacy, biomedical sciences, and pharmaceutical industry backgrounds enrolled in the programme. Two formative assessments and interactive activities ensured outcome-based learning and competency development aligned with national vigilance programmes. Participant feedback was overwhelmingly positive, highlighting the expert faculty, practical relevance, and the effective blended-learning approach of the course.









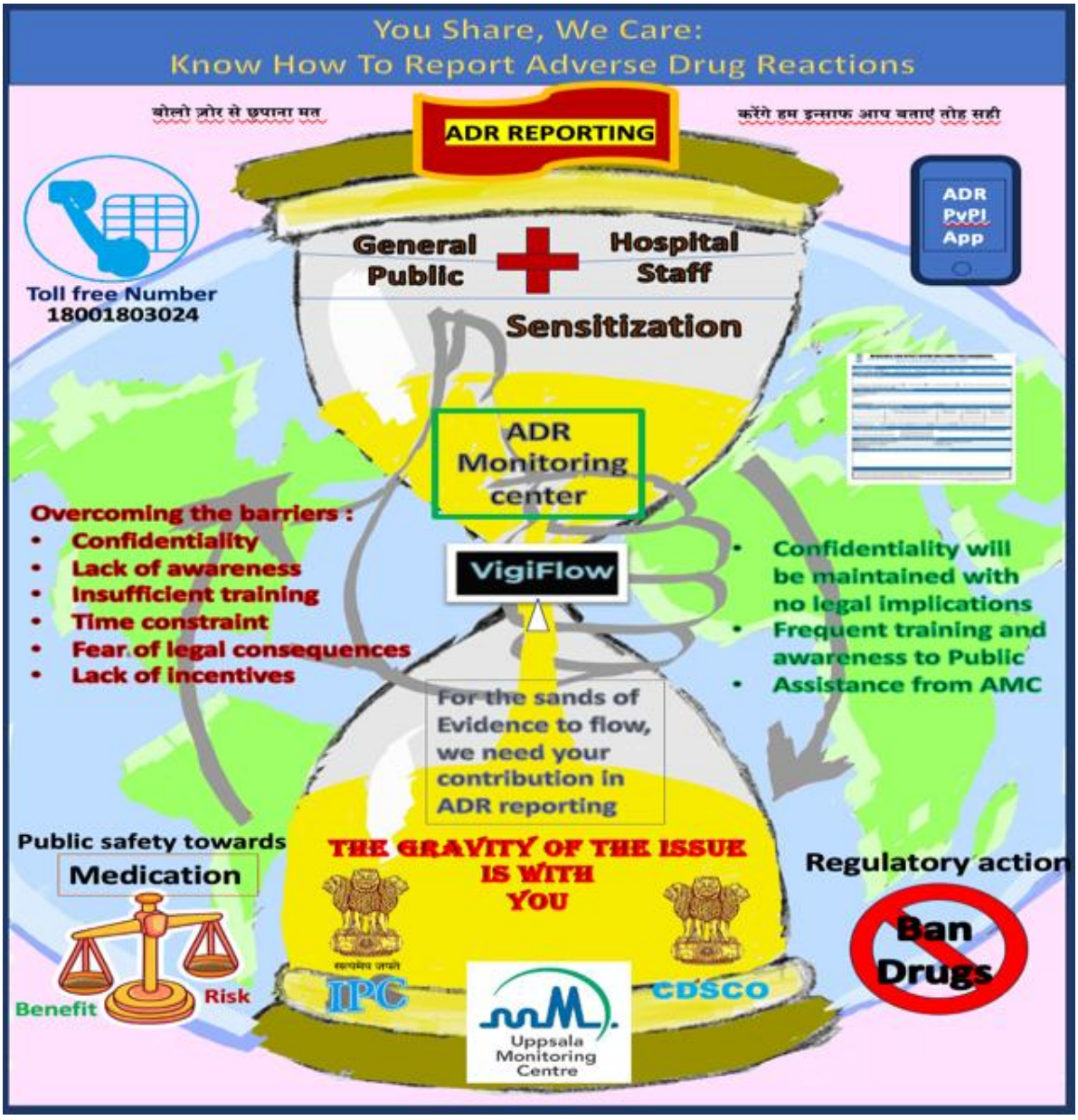
RECENT UPDATES FROM IPC

The Indian Pharmacopoeia Commission (IPC), in collaboration with the Kalam Institute of Health Technology (KIHT), organized the 1st Annual Meet of Regional Centres of PvPI & MvPI at the Kalam Convention Centre, AMTZ, Visakhapatnam, on 27th and 28th February 2026. The meeting focused on strengthening coordination among regional centres, enhancing adverse event reporting, improving data quality, and sharing regulatory and pharmacovigilance updates. The program also aimed to build capacity among healthcare professionals and promote collaborative strategies to advance patient safety and medical product vigilance activities across India.

SRMC PHARMVIGIL 2026

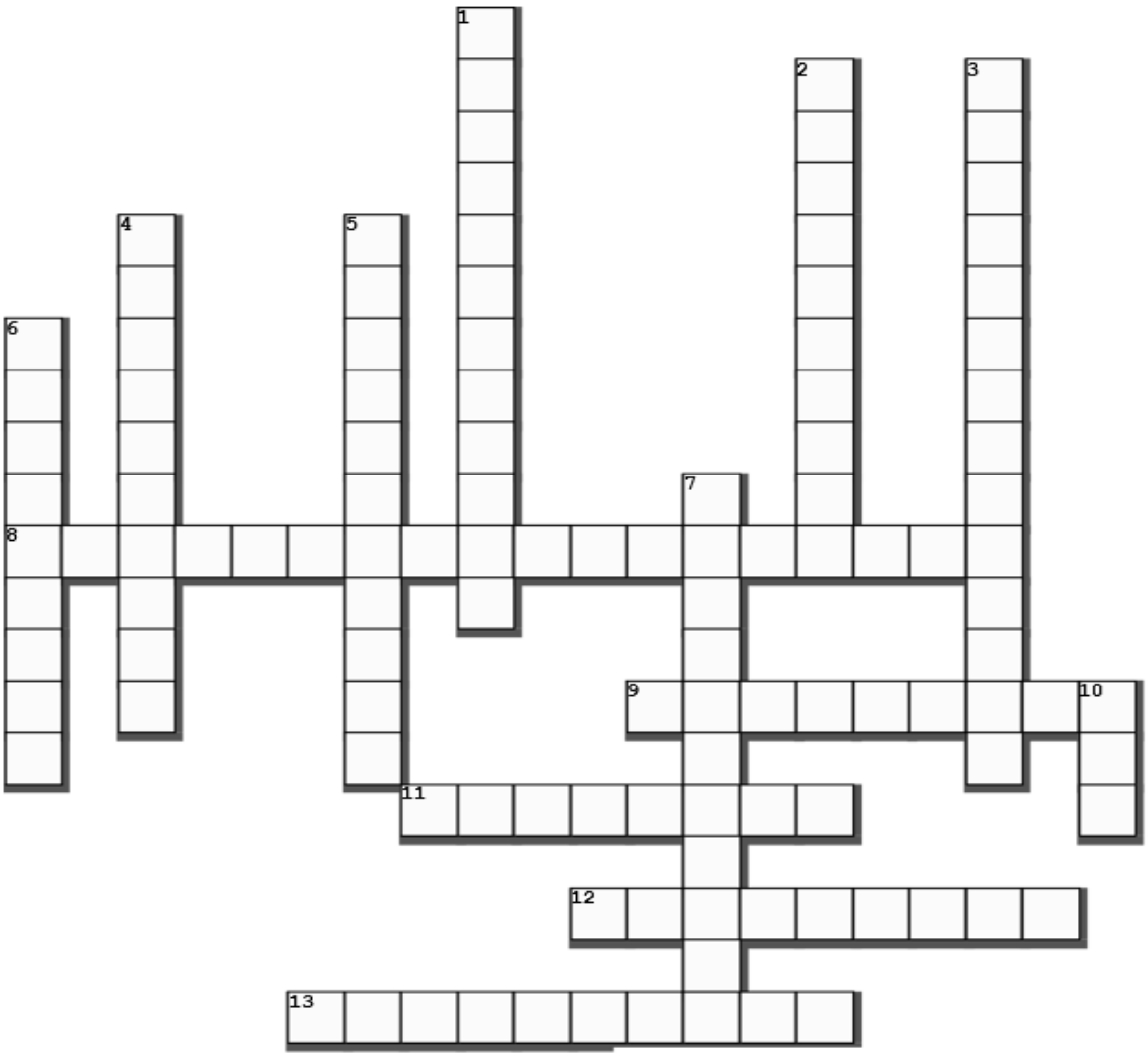
BRAIN STORMING CARTOON

Dr Calvin
Dr. Deepan
Final Year Postgraduate



CROSSWORD PUZZLE 1 - ANTIPSYCHOTICS

Dr.Suvarna Jyothi Kantipudi
Professor, Department Of Psychiatry



ACROSS

8.Common endocrine adverse effect due to dopamine blockade in the tuberoinfundibular pathway, causing galactorrhoea or amenorrhea

9.Neurotransmitter system antagonized by atypical antipsychotics through 5-HT_2A receptor blockade.

11.Primary neurotransmitter antagonized by first-generation antipsychotics to exert therapeutic effects.

12.Atypical antipsychotic associated with agranulocytosis, requiring mandatory absolute neutrophil count monitoring.

13.Skeletal muscle relaxant used as the drug of choice in the management of neuroleptic malignant syndrome.

DOWN

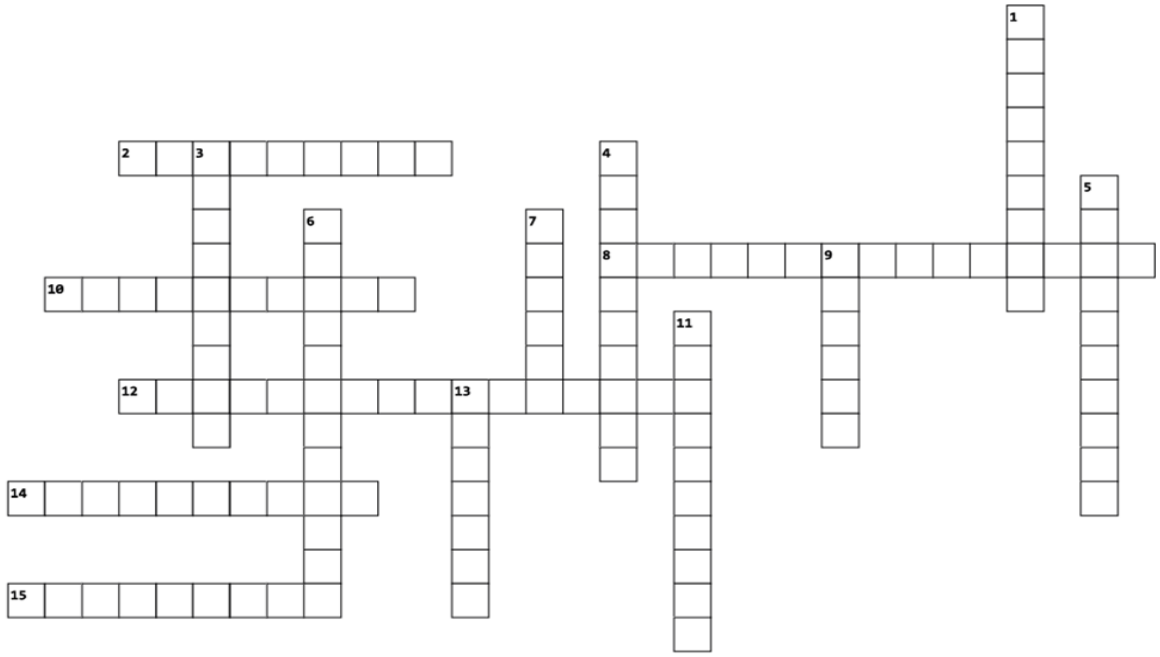
1.Second-generation antipsychotic acting as a partial dopamine D_2 agonist; akathisia is a common adverse effect.
2.Atypical antipsychotic frequently linked to significant weight gain and metabolic adverse effects.
3.Low-potency first-generation antipsychotic notable for marked sedation and anticholinergic adverse effects.
4.Atypical antipsychotic with minimal extrapyramidal symptoms, frequently causing somnolence and orthostatic hypotension.
5.High-potency first-generation antipsychotic associated with QTc prolongation and ventricular arrhythmias.
6. Extrapyramidal adverse effect characterized by subjective inner restlessness and inability to remain still.

7.Second-generation antipsychotic commonly associated with hyperprolactinemia and dose-related extrapyramidal adverse effects.

10.Life-threatening idiosyncratic reaction characterized by hyperthermia, muscle rigidity, and autonomic instability.

CROSSWORD PUZZLE - 2

Dr. Tejas
Dr Natasha
Final Year PG



Across

2. Antiretroviral boosted intentionally by CYP3A4 inhibition
8. The 'Grey Baby Syndrome' is a well-known ADR associated with which antibiotic in neonates due to their immature glucuronidation capacity
10. H_2 blocker withdrawn over NDMA impurity
12. Toxic excipient contaminant linked to fatal paediatric cough syrup outbreaks
14. Specific form to compile a spontaneous report of drug toxicity in the United Kingdom
15. Assessment of drug event relationship

Down

1. In 2004 this NSAID was shown to increase risk of heart attack and stroke leading to its withdrawal from the market
3. A drug that causes fetal abnormalities when administered to a pregnant woman
4. This drug is notorious for causing 'Red Man Syndrome', a pseudoallergic reaction, if infused too rapidly
5. Congenital limb defect classically linked to thalidomide
6. A genetically determined abnormal reactivity to a drug is best described as
7. Information suggesting a possible drug event link
9. Standardized medical terminology for safety reporting
11. Drug contraindicated with nitrates due to profound hypotension
13. Name of the MDAE reporting system used in the European Union Online

POEM

Dr. A. Jannathul Firdouse
Dr Sandeep K
Second Year PG

In every dose and every pill, we take,
A promise made for healing's sake,
Pharmacovigilance will ensure and improve,
Patient safety - our constant move.
From trial halls to market's bustling floor,
We watch for risks not seen before,
Adverse effects and signals in the flow,
Protecting lives with every case we know.
The patient's voice, the doctor's keen report,
Vigilant systems through which concerns are brought,
We ensure their safety, improve each day,
Guiding medicines along the safest way.
Remember Thalidomide's tragic tale,
When vigilance and systems seemed to fail,
That lesson taught us: never cease to see,
Improving safety for humanity.
Drug interactions, rare reactions too,
Emerge when populations grow from few,
Real-world data tells what trials cannot show,
Ensuring safety as the numbers grow.
Black box warnings, labels we refine,
Dose adjustments drawn from careful sign,
Each improvement saves another life,
Reducing suffering, minimizing strife.
Pharmacovigilance the watchful eye,
Ensuring safety, standards high,
Forever improving, never sleeping through,
Patient safety, our promise true.

UNSCRAMBLE

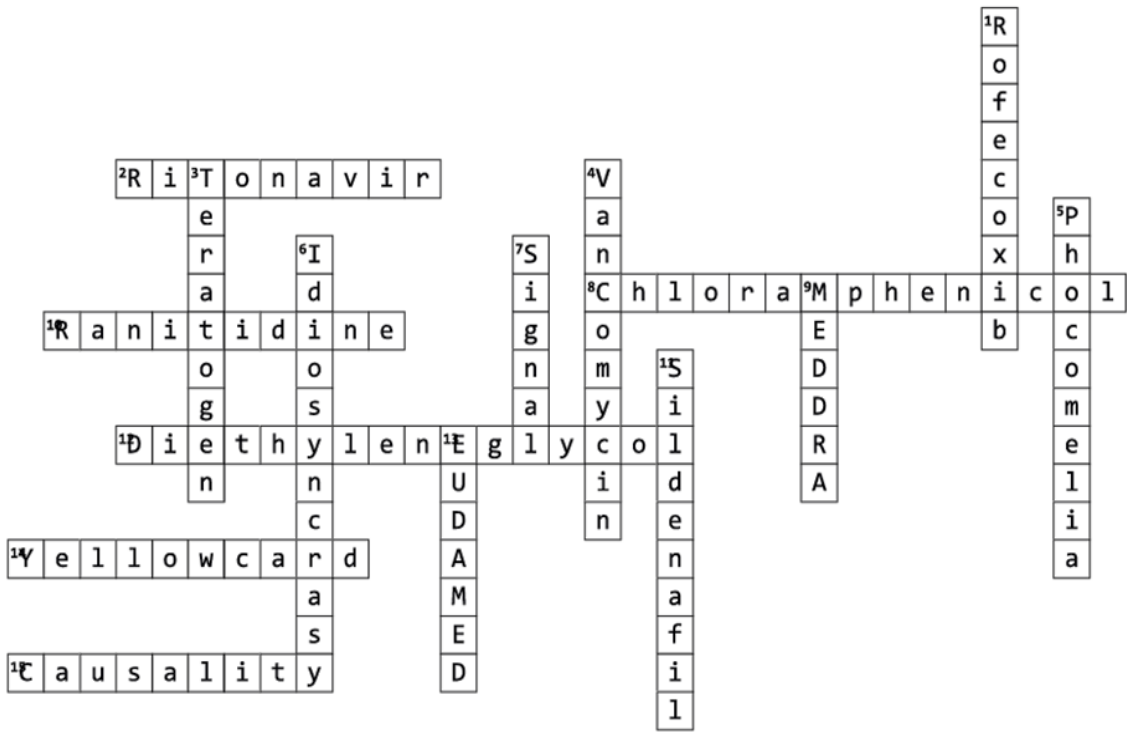
Dr. M.R. Raja Mohan
Dr Ram Prabakar
Second Year PG

1. The science of detecting, assessing, preventing drug harms – **CPHRAAGIMNVOLACEI**
2. The process used to uncover emerging safety patterns — **LNGIAS EDCITENOT**
3. A structured approach to determine if a drug caused a reaction — **SIATCAUYL TSEASNMSESE**
4. Monitoring system for device safety — **EITRMAVNICLOEIGA**
5. Continuous safety evaluation after Drug approval — **TOSP-GNKTIMAR ECAENILLVSUR**
6. Regulatory periodic safety summary — **RIDEOCIP YSETAF EDPUTA OPRTRE**
7. Official action to withdraw unsafe product — **LACRLE**
8. WHO centre for global signal work — **PSLAAUP NRMOTOING ETENCR**
9. WHO global adverse event database — **GBAISVIE**
10. Stopping a suspected drug — **DEHACLENLEG**
11. Any medical occurrence during drug use (regardless of cause) — **DVRESEA TEENV**
12. Safety incident that nearly caused harm — **NRAE SSMI**
13. Severe immune-mediated reaction — **YVIRIETENTHIYSPS**
14. Reduced response after repeated exposure — **LOTERANEC**
15. Airway-compromising allergic emergency — **HANYLAACTPIC RNTIOAEC**

ANSWERS
CROSS WORD

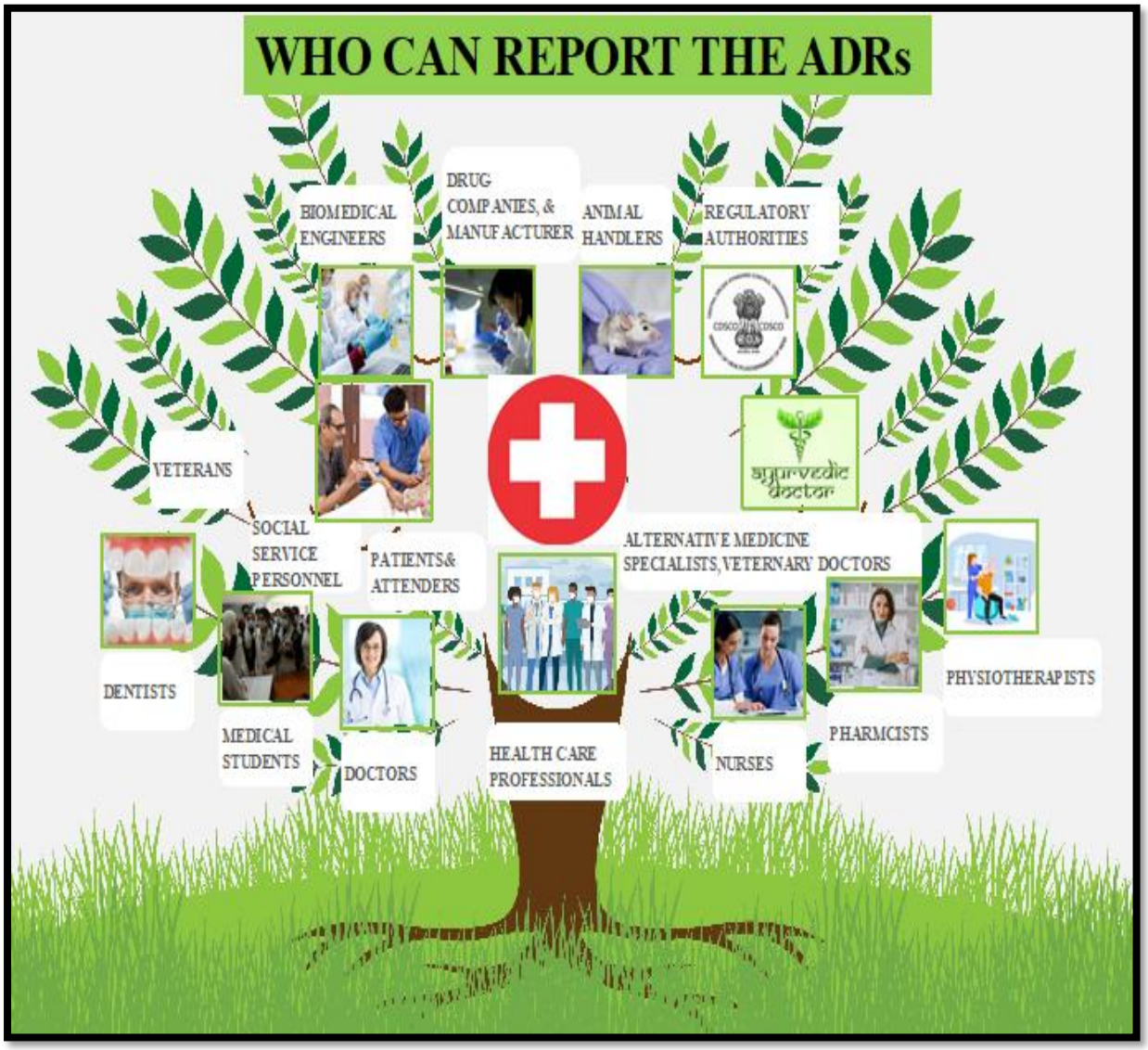
CROSSWORD PUZZLE - 1 ANTIPSYCHOTICS

CROSSWORD PUZZLE- 2



UNSCRAMBLE ANSWERS:

1. Pharmacovigilance
2. Signal Detection
3. Causality Assessment
4. Materiovigilance
5. Post-Marketing Surveillance
6. Periodic Safety Update Report (PSUR)
7. Recall
8. Uppsala Monitoring Centre
9. Vigibase
10. Dechallenge
11. Adverse Event
12. Near Miss
13. Hypersensitivity
14. Tolerance
15. Anaphylactic Reaction


WHO CAN REPORT THE ADRs
BIOMEDICAL ENGINEERS
DRUG COMPANIES, & MANUFACTURER
ANIMAL HANDLERS
REGULATORY AUTHORITIES
VETERANS
SOCIAL SERVICE PERSONNEL
PATIENTS& ATTENDERS
ALTERNATIVE MEDICINE SPECIALISTS, VETERNARY DOCTORS
DENTISTS
MEDICAL STUDENTS
DOCTORS
HEALTH CARE PROFESSIONALS
NURSES
PHARMCISTS
PHYSIOTHERAPISTS

For any suggestions/comments kindly mail to

hod.pharmacology@sriramachandra.edu.in

SRMC PHARMVIGIL 2026

ANNEXURE

Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

FOR AMC / NCC USE ONLY

Reg. No. / IPD No. / OPD No. / CR No. :

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION *

1. Patient Initials:

2. Age or date of birth:

3. Gender: M ☐ F ☐ Other ☐

4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)

6. Event / Reaction stop date (dd/mm/yyyy)

7. Describe Event/Reaction management with details , if any

12. Relevant investigations with dates :

13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)

14. Seriousness of the reaction : No ☐ if Yes ☐ (*please tick anyone*)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life threatening ☐ Disability

☐ Hospitalization-Initial/Prolonged ☐ Other Medically important

15. Outcome:

☐ Recovered ☐ Recovering ☐ Not Recovered

☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
i											
ii											
iii											
iv#											

9. Action taken after reaction (*please tick*)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

10. Reaction reappeared after reintroduction of suspected medication (*please tick*)

Yes	No	Effect unknown	Dose (if re-introduced)

11. Concomitant medical product including self-medication add herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
i							
ii							
iii#							

Additional Information :

D. REPORTER DETAILS *

16. Name & Address : _____

_____

Pin : _____ Email : _____

Contact No- : _____

Occupation : _____ Signature : _____

17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information

* Mandatory Fields for suspected ADR Reporting Form

ANNEXURE

ADVICE ABOUT REPORTING

A. What to report?

All adverse events should be reported

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines & Herbal Products.

Report every serious adverse drug reactions. A reaction is serious when the patient outcome is :

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Report intervention to prevent permanent impairment or damage

NOTE : Serious/Adverse Event following immunization can also be reported in Serious AEFI case Notification Form available on http://www.ipc.gov.in

B. Who can report?

All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurse etc.) can report adverse drug reactions

C. Where to report?

Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC) for PvPI.

Call on Helpline (Toll Free) 1800 180 3024 to report ADRs or directly mail this filled form to pvpi.ipc@gov.in

A list of nationwide AMCs is available at : http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D.What happens to the submitted information?

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The Signal Review Panel of PvPI reviews the data and suggests any interventions that may be required.

E. Mandatory fields for suspected ADR Reporting Form (*)

Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) & reporter information.

For Adverse Drug Reaction Reporting Tools

- **E-mail : pvpi.ipc@gov.in**
- **PvPI Helpline (Toll Free) : 1800 180 3024** (9:00 AM to 5:30 PM, Monday-Friday)
- **ADR Mobile App : "ADRPvPI"**

NOTIFICATION SLIP FOR SUSPECTED ADVERSE DRUG REACTION FROM SRIRAMACHANDRA MEDICAL COLLEGE & HOSPITAL

SRI RAMACHANDRA HOSPITAL

ADVERSE DRUG REACTION MONITORING CENTRE

DEPARTMENT OF PHARMACOLOGY, SRI RAMACHANDRA MEDICAL COLLEGE & RESEARCH INSTITUTE
SRI RAMACHANDRA UNIVERSITY, PORUR, CHENNAI - 600 116. Email : adrarmc@gmail.com

NOTIFICATION OF SUSPECTED ADVERSE DRUG REACTION FORM **CONFIDENTIAL**
(As per CDSCO, Ministry of Health & Family Welfare, Govt. of India)

Patient Name : Age: Sex: I.P/O.P No: Unit/Dept:

Suspected drugs/vaccines Generic name: Trade name: Batch No:

Concomitant drugs:

Diagnosis for use:

Outcomes: Fatal ☐ Recovering ☐ Recovered ☐ Continuing ☐ Unknown ☐ Others(specify) ☐

Drug started on: Drug stopped on: Date of reaction:

Brief description of reaction:

Name of the Doctor/Reporter: Signature: Date:

Please drop it in ADR drop box at DMS office (OP building) or DNS office (IP building)

SRI RAMACHANDRA PHARMACOVIGILANCE CENTRE

ADVERSE DRUG REACTIONS MONITORING CENTRE OF PvPI

PLEASE REPORT

Adverse Drug reactions

(Known or unknown, Serious or Non-Serious, Frequent or Rare)

Associated with Medicines, Medical Device, Blood Products, Vaccine and Herbal

To

Adverse Drug Reaction Monitoring Centre, Sri Ramachandra Medical College, Porur, Chennai.

Dr. R. Kavitha M.D., **HOD & Coordinator** **SRMC-AMC** **Ph No: 9444551410** **Email:** **hod.pharmacology@sriramachandra.edu.in**	**Dr. D. Anusha M.D.,** **Deputy Coordinator** **SRMC-AMC** **Ph No: 9884313112** **Email:** **pharmacovigilance@sriramachandra.edu.in**	**Dr. S. Karunika Pharm.D.,** **Pharmacovigilance Associate** **SRMC-AMC** **Ph No: 9790928901** **Email:** **pharmacovigilance@sriramachandra.edu.in**

DEPT OF PHARMACOLOGY

CONTACT NUMBER - 044 2476 8027: EXTENSION NUMBER – 226/223