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FROM THE EDITOR'S DESK

The clinical research landscape is undergoing a profound and rapid transformation, driven by advancements in technology, shifting regulatory expectations, and a growing emphasis on patient-centred approaches. As we move through 2025, innovations such as artificial intelligence, decentralized clinical trials (DCTs), wearable health devices, and real-world evidence (RWE) are reshaping how we design and conduct trials.

These advancements are not just enhancing operational efficiency—they are redefining timelines, improving data accuracy, and expanding access to underserved populations. Particularly, the rise of decentralized and hybrid trial models has made it possible for patients to participate from virtually anywhere, breaking down traditional barriers such as geography, mobility, and healthcare access.

Yet, with innovation comes responsibility. Patient safety must remain the bedrock of every clinical trial, regardless of how advanced or digitalized the process becomes. Real-time safety monitoring, robust pharmacovigilance systems, and ethical oversight are essential to safeguard participants while ensuring data integrity and compliance with global regulations.

The clinical research industry continues to add tremendous value to society. It is the driving force behind the development of new medicines, vaccines, and therapies that save lives and improve quality of life. Beyond its scientific contributions, the industry also supports economic development, creates high-skill jobs, and fosters global collaboration across disciplines.

Furthermore, increasing diversity in clinical trials is a critical priority. By ensuring representation across age, gender, race, and geography, we can improve the relevance and applicability of research outcomes for all patient populations. As researchers, sponsors, and regulators, we share a collective responsibility to innovate with purpose. Let us continue to push boundaries while upholding the highest standards of ethics, quality, and safety—with patients always at the centre of everything we do.

I am happy to present before you the SCRMP Annual Magazine 2025.

Happy Reading.

Gurpreet Singh
Vice President, Managing Director
Integrated Safety at IQVIA United Kingdom &
Honorary Global President of SCRMP

SCRMP PAST EVENT HIGHLIGHTS

ಕಲಬುರಗಿ: ನಗರದ ಎಂ.ಆರ್.ಎಂ.ಸಿ ಸ್ಕಾಕ್ ಕಟ್ಟಡದಲ್ಲಿ ಇಂದು ಹಮ್ಮಿಕೊಂಡಿದ್ದ
ಅಂತರರಾಷ್ಟ್ರೀಯ ಕಾನ್ಫ್ಲೇವ್-೨೦೨೫ ಜರುಗಿತು. ಎಸ್.ಸಿಆರ್.ಎಂ.ಪಿ
ಅಧ್ಯಕ್ಷ ಗುರುಪ್ರೀತ್ ಸಿಂಗ್, ಶಶೀಲ ನಮೋಶಿ, ಪುನಂಕುಮಾರಿ,
ಮೊಹಮ್ಮದ ಗಯೂರ್, ಖಾನ್, ನಿಖಿಲ್ ಭಾನುಮತಿ ಇದ್ದರು.

- Dr. Shipra Sehgal

DIGITAL TRANSFORMATION IN CLINICAL RESEARCH: CATA-LYZING A NEW PARADIGM IN DRUG DEVELOPMENT

The integration of digital technologies into clinical research processes is fundamentally reshaping the drug development landscape. From decentralized clinical trials (DCTs) to AI-driven analytics and blockchain-enabled data management, digital transformation is enhancing operational efficiency, accelerating timelines, and fostering patient-centric approaches. This article examines the principal drivers of digital innovation in clinical research, highlights representative industry initiatives, and discusses both the opportunities and ongoing challenges associated with this transformation.

Introduction

Clinical research is the foundation of evidence-based therapeutic innovation, yet it has historically been hindered by operational inefficiencies, protracted timelines, and challenges in patient recruitment and retention. In recent years, the adoption of digital technologies has catalyzed significant advancements in trial design, execution, and oversight. The COVID-19 pandemic further underscored the necessity for resilient, flexible, and patient-friendly research models, accelerating the adoption of decentralized and digital approaches.

Key Dimensions of Digital Transformation in Clinical Research

1. Decentralized Clinical Trials (DCTs)

DCTs leverage telemedicine, remote monitoring, mobile applications, and wearable sensors to enable the conduct of clinical studies outside traditional investigator sites. This model has demonstrated the potential to improve patient access, enhance recruitment diversity, and optimize trial efficiency.

Industry Example:

Pfizer's REMOTE trial (2011) served as one of the earliest fully virtual studies, assessing a therapeutic for overactive bladder through a digital platform. More recently, Novartis adopted hybrid decentralized models during the COVID-19 pandemic, incorporating e-Consent solutions and remote patient monitoring to maintain study continuity.

2. Real-World Data (RWD) Integration and AI-Driven Analytics

The integration of RWD — including data from electronic health records (EHRs), patient registries, and connected devices — with clinical trial data offers a more comprehensive understanding of treatment outcomes. AI and machine learning (ML) technologies facilitate predictive analytics for site selection, patient identification, risk-based monitoring, and adaptive trial designs.

- Dr. Shipra Sehgal

Industry Example:

Roche's acquisition of Flatiron Health in 2018 allowed access to a robust, oncology-specific real-world evidence platform, supporting both clinical and regulatory strategies. Likewise, IQVIA has deployed AI-based algorithms to improve patient recruitment workflows and optimize operational oversight.

3. Blockchain Technology for Data Integrity and Transparency

Blockchain offers a decentralized, tamper-evident framework for clinical data management, enhancing transparency, auditability, and trust among trial stakeholders.

Industry Example:

Boehringer Ingelheim collaborated with IBM in Canada to implement a blockchain pilot for clinical trial consent management, improving the security and traceability of consent documentation.

4. Digital Patient Engagement and e-Consent Solutions

Modern clinical trials increasingly prioritize patient convenience and engagement through digital platforms, including e-Consent systems, mobile health applications, and patient portals. These tools improve comprehension, facilitate continuous communication, and support adherence monitoring.

Industry Example:

Medable and Signant Health have developed integrated e-Consent and patient engagement solutions tailored for decentralized and hybrid trial models, significantly enhancing the patient experience and regulatory compliance.

Challenges and Considerations

Despite the evident advantages of digital transformation, several challenges persist:

- **Data security and privacy:** The increased volume and sensitivity of digital patient data necessitate stringent cybersecurity and privacy safeguards.
- **Regulatory harmonization:** Consistent, global regulatory frameworks for digital tools are required to ensure compliance and interoperability.
- **Digital literacy and access disparities:** Varying levels of digital proficiency among patients and clinical staff, along with unequal access to digital infrastructure, may limit the widespread implementation of digital trial solutions.
- **Change management and organizational readiness:** Successful adoption of digital technologies requires comprehensive change management strategies and upskilling initiatives within sponsor organizations and CROs.

- Dr. Shipra Sehgal

Future Perspectives

The future of clinical research will likely feature increased adoption of:

- **Fully virtual trials** for select indications and patient populations.
- **Digital biomarkers** derived from wearable devices and mobile health technologies.
- **AI-powered adaptive trial designs**, enabling real-time protocol modifications based on interim data.
- **Interoperable health data ecosystems** facilitating seamless integration of RWD and trial data for regulatory submissions.

As digital technologies mature and regulatory frameworks evolve, the convergence of clinical research with digital health will redefine industry standards for efficiency, patient engagement, and data-driven decision-making.

Conclusion

Digital transformation represents a pivotal shift in clinical research, offering the potential to overcome longstanding operational challenges and enhance patient-centricity. While technological innovations such as decentralized trials, AI-driven analytics, and blockchain-enabled data management present significant opportunities, their successful implementation necessitates careful navigation of data governance, regulatory, and operational complexities. Sustained collaboration among sponsors, technology providers, regulatory agencies, and patient advocacy groups will be essential to fully realize the benefits of digital transformation in clinical development.

References

1. Pfizer. (2011). The REMOTE Virtual Clinical Trial. Retrieved from https://www.pfizer.com
2. Roche. (2018). Flatiron Health Acquisition. Retrieved from https://www.roche.com
3. Novartis. (2020). COVID-19 Response: Embracing Digital Trials. Retrieved from https://www.novartis.com
4. Boehringer Ingelheim. (2019). Blockchain Pilot for Consent Management. Retrieved from https://www.boehringer-ingelheim.com
5. IQVIA. (2023). Virtual Trials and AI Solutions. Retrieved from https://www.iqvia.com
6. Medable. (2022). Decentralized Trial Technology Solutions. Retrieved from https://www.medable.com

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- Punam Kumari

DECENTRALISED CLINICAL TRIALS: A NEW ERA IN PATIENT-CENTRIC RESEARCH

The landscape of clinical research is undergoing a profound transformation with the emergence of Decentralised Clinical Trials (DCTs) (also known as virtual clinical trials), marking a pivotal shift toward patient-centricity. The randomised controlled trial (RCT) that has long been considered the gold standard in clinical research is a model where participants undergo thorough screening, treatment, and monitoring at designated study sites. While RCT ensures strict oversight and controlled study conditions, it also presents challenges, including high costs and limited accessibility for participants, leading to participation disparities. Likewise, other well-established trials also frequently encounter obstacles like geographic limitations, limited participant diversity, and logistical difficulties, which can hinder both participant involvement and long-term retention. Unlike these standard and conventional trials, the approach of DCT is centred around the patient, prioritising their convenience and engagement. It incorporates digital innovations such as electronic consent (e-consent), mobile applications, wearable technologies, electronic patient-reported outcomes (ePRO), and telemedicine. Additionally, it shifts various trial activities from traditional clinical sites to more accessible locations like the patient's home, through services such as drug delivery, or nearby community healthcare facilities for diagnostics and care. DCTs are made to fit around patients' everyday lives. They let people take part no matter where they live by removing travel and other practical issues. This makes it easier for more people to join the study and try the treatment, including those from different backgrounds.

The concept of DCTs has been around for some time and is not entirely a novel development. The idea of running clinical trials online started as early as 2003, with the first patented "Trial over the Internet" in 2007. In 2011, Pfizer ran the first fully decentralised trial called REMOTE, where everything—from sign-up to treatment delivery—was done online or at the patient's home. Over the past ten years, all major pharmaceutical companies have used decentralised methods. Before the COVID-19 pandemic, less than half of industry experts expected most trials to be virtual or home-based. But one year into the pandemic, nearly all of them did. A 2020 survey showed that 76% of companies were using decentralised trial methods, with 7% running fully virtual studies. COVID-19 played a big role in proving that decentralised trials can work well, especially in urgent situations.

Compared to traditional approaches, decentralised studies provide a wide range of benefits. Most notably, they are especially well-suited for trials involving chronic or rare diseases, participants with limited mobility, self-administered investigational drugs, a lower safety risk profile and confirmatory clinical trials. This approach can help reduce the stress on the sick participants, who would otherwise have to invest time and money to travel, potentially increasing their exposure to additional health risks.

- Punam Kumari

Since DCTs are not tied to specific research centres, this allows for tapping into a much broader pool of potential participants who can be recruited and screened online. This approach makes the process faster, safer and ensures the right participants are selected. Further, having participants from a wider geography increases diversity, improves the generalisability of the results, and speeds up recruitment.

This method enables the participants to adopt convenient methods of submitting their electronic consent through various methods, including online platforms or by phone, making participation more accessible. Additionally, with fewer physical trial sites involved, there are reductions in the number of institutional review boards required, which in turn lowers regulatory and operational costs, training demands, monitoring costs and protocol amendment complexities.

Remote evaluations carried out by a small and consistent team of investigators help minimise variability and can lead to smaller and more efficient studies. Technologies such as video consultations and in-home health visits support effective oversight and early identification of safety concerns, enabling more frequent and long-term monitoring. Ultimately, this model supports the collection of more continuous, real-world-like data that enhances the relevance and quality of trial findings.

Therefore, DCTs undoubtedly hold great potential to enhance the efficiency and reach of clinical research. However, they also come with a set of significant challenges that must be addressed. A major concern involves regulatory and compliance issues, which vary across different regions. Since DCTs are conducted across multiple jurisdictions, they must navigate varying regulatory requirements related to remote monitoring, data protection, electronic informed consent, and the validation of digital endpoints for regulatory submissions.

Another critical challenge is the integration of technology and managing data security risks. DCTs depend heavily on digital tools such as wearables, telemedicine, and mobile platforms, which raise concerns about cybersecurity, data privacy, and system interoperability. Ensuring robust data encryption, aligning various digital systems for smooth data exchange, and managing technical glitches are essential to maintain data quality and regulatory compliance.

In addition, logistics such as managing the drug supply chain to patients and ensuring consistent training and coordination across dispersed teams can be complex. Lastly, patient engagement and compliance remain pivotal challenges. While DCTs improve trial accessibility, they also demand greater patient responsibility in self-monitoring and data submission. This can be especially difficult among older participants or those with limited digital literacy. Maintaining engagement throughout long-term studies, closing the digital skills gap, and fostering trust around data use and transparency are essential to the success of decentralised trials.

- Punam Kumari

Conclusion

To wrap up, for DCTs to be successfully implemented, several key components must come together. These include having the right infrastructure and personnel, clear regulatory guidance, and strong collaboration among research sites, patients, and sponsoring organisations. Central to this is the formation of multidisciplinary teams with expertise in clinical research, regulatory affairs, technology development, data science, and community health advocacy. Bringing together such diverse skill sets fosters innovative solutions to address the complex challenges of DCT implementation. As digital tools alone may not be sufficient, access to dedicated support teams is also essential. Ultimately, the future success of DCTs relies on the collective commitment and collaboration of all stakeholders to make clinical research more inclusive, equitable, and effective in improving health outcomes for all.

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- John Praveen

HARNESSING ARTIFICIAL INTELLIGENCE TO TRANSFORM AGGREGATE REPORTING AND MEDICAL WRITING

Introduction

The pharmaceutical and healthcare industries are undergoing a profound transformation thanks to advances in Artificial Intelligence (AI). Among the many domains impacted, aggregate safety reporting and medical writing stand out as areas where AI is making a significant difference. These functions have traditionally been resource-intensive, requiring painstaking manual efforts to compile, analyze, and document data. However, AI technologies are now streamlining these processes, driving improvements in efficiency, accuracy, and regulatory compliance. This shift is enabling pharmaceutical companies to accelerate timelines, reduce costs, and ultimately enhance patient safety.

The Evolution of Aggregate Reporting with AI

Aggregate reporting plays a critical role in pharmacovigilance by providing a comprehensive overview of a drug's safety profile over time. It involves the collection, integration, and analysis of large volumes of data from multiple sources such as clinical trials, spontaneous adverse event reports, electronic health records, and published literature. The goal is to detect safety signals, monitor known risks, and comply with regulatory requirements through periodic safety update reports (PSURs), development safety update reports (DSURs), and other aggregate safety documents. Historically, compiling these reports has been a laborious process involving manual data extraction, validation, and review by safety professionals.

AI is revolutionizing aggregate reporting by enabling automation and intelligent data handling at unprecedented scales. Machine learning algorithms can now aggregate and harmonize data from heterogeneous sources far more quickly and accurately than traditional manual methods. These AI-driven systems identify patterns and correlations within the data that may go unnoticed by human reviewers, facilitating earlier detection of potential safety signals. For example, natural language processing (NLP) techniques can scan narrative text in adverse event reports and medical literature to extract relevant safety information automatically. This enhances the depth and breadth of data considered in aggregate reports, providing richer insights into drug safety.

Furthermore, AI improves data quality by automatically identifying discrepancies, missing information, or duplicate entries, which are common challenges in pharmacovigilance datasets. This automated data cleansing reduces the risk of errors and increases confidence in the conclusions drawn from aggregate reports. Another important aspect is regulatory compliance: AI tools can be trained to recognize the complex and evolving regulatory guidelines that govern safety reporting worldwide.

- John Praveen

By embedding regulatory knowledge into AI systems, pharmaceutical companies can ensure that their aggregate reports meet the required standards, reducing the likelihood of regulatory queries or delays.

Transforming Medical Writing with Artificial Intelligence

In parallel, AI is transforming medical writing — a crucial function responsible for generating the textual documents that communicate clinical trial results, safety data, and regulatory submissions. Medical writing demands scientific accuracy, clarity, and consistency, often under tight deadlines. The drafting of clinical study reports, safety narratives, and submission dossiers is typically time-consuming and prone to human error. AI-powered language models are now providing a solution by generating initial drafts based on structured data inputs and predefined templates. This capability significantly reduces the time needed for first drafts and allows medical writers to focus more on refining and contextualizing the content rather than starting from scratch.

Beyond draft generation, AI contributes to content standardization by ensuring consistent terminology, style, and formatting across large volumes of documents. This consistency is vital for readability and compliance, especially when multiple authors or teams contribute to a single submission package. Advanced AI proofreading and editing tools also help detect grammatical mistakes, inconsistencies, or potential regulatory non-compliance issues, further enhancing document quality. Additionally, AI-powered literature review tools scan vast amounts of scientific publications to extract and summarize relevant information, supporting evidence-based writing without the exhaustive manual effort previously required.

Benefits of AI Integration in Safety Reporting and Writing

One of the key advantages of integrating AI into aggregate reporting and medical writing is the considerable efficiency gain. Automation of routine and repetitive tasks accelerates the overall process, helping pharmaceutical companies bring safer drugs to market faster. This speed is not merely a competitive advantage but a crucial factor in improving public health outcomes. At the same time, AI reduces the human workload and fatigue associated with data-intensive pharmacovigilance activities, lowering the risk of oversight or errors that could compromise patient safety.

Accuracy is another critical benefit. Machine learning models, when properly trained and validated, can detect subtle patterns and anomalies that humans might miss. This capability enhances signal detection and risk assessment, providing a more robust foundation for regulatory decisions. The integration of AI also leads to cost savings by minimizing the need for extensive manual review and rework, streamlining the entire safety reporting and medical writing workflow.

- John Praveen

Challenges and Considerations for AI Adoption

Despite these advantages, several challenges remain in fully realizing AI's potential in these areas. Data privacy and security are paramount, given the sensitive nature of clinical and patient information involved. Pharmaceutical companies must ensure robust safeguards to protect data while enabling AI systems to function effectively. Moreover, regulatory authorities are still evolving their frameworks around AI-driven documentation, emphasizing the need for transparency and explainability in AI algorithms. Human oversight remains indispensable; AI should augment expert judgment, not replace it. Medical writers, safety physicians, and pharmacovigilance specialists play an essential role in reviewing and validating AI-generated outputs.

Bias in AI models also poses a concern. If the training data is not representative or contains inherent biases, the AI system might produce skewed results, potentially impacting safety signal detection or the quality of written documents. Careful model development, validation, and ongoing monitoring are necessary to mitigate such risks. Lastly, the adoption of AI requires organizational change management and training to ensure that teams can effectively leverage these new tools.

The Future Outlook of AI in Pharmacovigilance and Medical Writing

Looking ahead, the future of pharmacovigilance and medical writing lies in the seamless integration of AI and human expertise. Emerging AI platforms increasingly offer end-to-end solutions that encompass data ingestion, signal detection, report generation, and document authoring in a unified environment. Explainable AI techniques are gaining traction to provide greater transparency and build trust with regulators and stakeholders. Furthermore, AI's capabilities are expanding to support multilingual medical writing, helping global pharmaceutical companies navigate diverse regulatory landscapes more efficiently.

Conclusion

Artificial Intelligence is transforming aggregate reporting and medical writing by automating complex tasks, enhancing data analysis, improving document quality, and ensuring regulatory compliance. While challenges related to data privacy, regulatory acceptance, and human oversight remain, the benefits of AI-driven innovation in these domains are compelling. By embracing AI as a powerful ally, pharmaceutical companies can unlock new levels of efficiency, accuracy, and safety in drug development and post-marketing surveillance, ultimately advancing healthcare outcomes for patients worldwide.

- John Praveen

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- Kelli Boyden

GLOBAL TALENT, NATIONAL NEED: HOW US DRUG SHORTAGES ARE REDEFINING US IMMIGRATION PRIORITIES

Medical patients in the US are persistently at risk because of drug shortages. Pharmacists who serve these patients are challenged to provide care while navigating shortage crises. Pediatric oncology drugs, generic injectables, and even sterile saline have all landed on the FDA's shortage list, not for lack of demand, but because of fragile supply chains, limited domestic production capacity, and workforce bottlenecks in pharmaceutical compliance and manufacturing.

This persistent vulnerability presents a surprising opportunity in US immigration law: the EB-2 National Interest Waiver (NIW) visa pathway. Originally designed to fast-track individuals whose work serves broad US interests, the EB-2 NIW now stands as a crucial tool in recruiting foreign-born experts who can help stabilize pharmaceutical infrastructure from the inside out. While current political rhetoric cuts against immigration, immigration is a matter of law governed by the Administrative Procedure Act. Therefore, valid changes require the intervention of Congress to change the law. Until then, the framework of immigration law is unchanged, and the action of immigration authorities are subject to judicial review. Unsuccessful attempts to thwart the law are, at worst, temporary. They should not discourage those with long-term immigration plans.

Math Meets Policy: A $35 Billion Bottleneck

The US Department of Homeland Security has found drug shortages cost each hospital system for $500,000 to $1 million annually, including labor costs attributed to pharmacists and clinicians scrambling to find alternatives or modify treatment protocols. While this impact is felt locally in the US, one cause is vulnerabilities to market fluctuation, transport hazards, and tariffs or other regulatory barriers to entry faced as the US imports over 80 percent of active pharmaceutical ingredients (APIs) from other countries, including India.

The shortage isn't only in APIs or finished dosage forms. The US also needs regulatory specialists, plant managers proficient in current good manufacturing practices (cGMP), formulation scientists, and pharmacovigilance experts. These roles often require 10+ years of experience and international training. Specialized immigration paths are a rich source for new residents who can bring professional ability.

Specific Gaps Petitioners Can Fill

International professionals considering the EB-2 NIW pathway may qualify by showing their work addresses a "matter of national importance."4 In the pharmaceutical context, that could include:

- Kelli Boyden

- Sterile injectable manufacturing: The US has only a handful of GMP-compliant facilities capable of scaling sterile injectables, and more solutions are needed to address shortages. Petitioners who can help retrofit, design, or staff such plants are directly addressing national needs.
- Plant-based or alternative APIs: Rising interest in botanical ingredients and plant-based actives presents a need for researchers with expertise in sustainable sourcing, extraction, and validation.
- Regulatory compliance and Drug Enforcement Administration oversight: Drug shortages are caused or prolonged by regulatory hurdles.3 Experts in risk evaluation and management strategies, 505(b)(2), or international good manufacturing regulations are in demand.
- Antimicrobial resistance (AMR): The CDC estimates 2.8 million infections and 35,000 deaths annually from AMR in the US. Scientists working on AMR-targeted therapies or diagnostics are central to national health priorities.
- Quality systems and risk mitigation: The FDA continues to cite U.S. firms for gaps in Quality by Design (QbD) and risk-based manufacturing. Quality assurance and quality control professionals from regulated markets may be key to strengthening compliance.

Why Onshoring Matters: The Case for National Benefit

As noted above, onshoring pharmaceutical manufacturing improves:
- Supply chain resilience
- Domestic job creation
- National security and patient access

EB-2 NIW petitioners can demonstrate that their entrepreneurial or specialized professional efforts in the US contribute highly specialized knowledge to support US-based API and finished drug production. Whether leading scale-up, solving regulatory logjams, or launching new sterile capacity, their work has national implications.

Example: Dr. L's Case (Anonymized and Simplified)

Dr. L*, a PhD in pharmaceutical sciences from India with over 15 years of experience in injectable biologics, filed an EB-2 NIW petition focused on consulting US startups converting from oral solids to sterile injectables. She highlighted:

- Regulatory experience, including with international agencies
- Letters of support from US firms needing her services
- A written plan for improving domestic capacity through tech transfer and scale-up

Her petition was approved in a reasonable time.

- Kelli Boyden

Estimated costs for Dr. L's case:

- Attorney fees: $7,500
- I-140 and premium processing: $3,505
- Document translation and evaluation: $350
- Medical exam (pre-consular interview): $275
- Consular fees and travel: ~$700

Total spent: ~$12,300 USD

She now works with multiple US-based biotech startups, helping bring sterile production online for shortage-prone injectables.

Visa Type	Best For	Self-Petition?	Employer Required?	Green Card?	What's Required
EB-2 NIW *(National Interest Waiver)*	Scientists, regulatory experts, innovators	☑ Yes	✗ No	☑ Yes	National importance + well-positioned plan
EB-5 (Direct Investment)	Founders creating U.S. jobs through pharma/supplement ventures	☑ Yes	✗ No	☑ Yes	$800k+ investment, 10+ jobs, business plan
O-1A *(Extraordinary Ability)*	Internationally recognized experts with major impact	☑ Sometimes	☑ Usually	✗ No (can lead to EB-1)	Awards, publications, significant contributions
EB-1A *(Extraordinary Ability Green Card)*	World-renowned pharma leaders	☑ Yes	✗ No	☑ Yes	Sustained acclaim, significant original work
H-1B *(Skilled Worker)*	U.S. employers hiring for scientific roles	✗ No	☑ Yes	✗ No (can adjust later)	Employer sponsorship + lottery cap
IEP *(International Entrepreneur Parole)*	Startup founders with U.S. investor backing	☑ Yes	✗ No	✗ No (renewable)	U.S. funding, innovation, job creation potential

- Kelli Boyden

Conclusion: Expertise as Infrastructure

When pharmaceutical professionals build safer, more resilient systems through manufacturing, regulatory science, or sustainable sourcing, they aren't just creating products. They are fortifying infrastructure. In doing so, they meet one of the most compelling immigration standards available: the national interest.

For the globally trained pharmacist, chemist, regulatory scientist, or botanist, the message is clear: your expertise is needed—not someday, but now.

References

1. Gallagher A. Survey: 50% of active drug shortages in the United States persist for 2 or more years. Pharmacy Times. November 1, 2024. Accessed December 21, 2024. https://www.pharmacytimes.com/view/survey-50-of-active-drug-shortages-in-the-united-states-persist-for-2-or-more-years
2. Juliette B, Robin C. Influence of drug shortages on the well-being at work of pharmacists practicing in community pharmacies. Explore Res Clin Soc Pharm. 2024 Jul 2;15:100471. doi: 10.1016/j.rcsop.2024.100471. PMID: 39092314; PMCID: PMC11292554.
3. US Food & Drug Administration. Drug shortages for calendar year 2023 (required by Section 506C–1 of the Federal Food, Drug, and Cosmetic Act). 2024. Accessed December 21, 2024. https://www.fda.gov/media/179156/download
4. US Citizenship and Immigration Services. Advanced degree or exceptional ability. Policy Manual. Updated April 2, 2025. Accessed April 11, 2025. https://www.uscis.gov/policy-manual/volume-6-part-f-chapter-5
5. Kleindienst v. Mandel, 408 US 753 (1972).
6. Reagan v. Abourezk, 484 U.S. 1, 1 (1987) (mem.).
7. US Senate Committee on Homeland Security & Governmental Affairs. Short supply: The health and national security risks of drug shortages. March 2023. Accessed April 11, 2025. https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf
8. Muzzio FJ. Overcoming global risk to the pharmaceutical supply chain for the United States: Achieving pharmaceutical independence by reshoring manufacturing capacity and capability. NIPTE. Published June 18, 2024. Accessed April 11, 2025. https://nipte.org/wp-content/uploads/2024/06/Overcoming-Global-Risk-to-the-Pharmaceutical-Supply-Chain_061824.pdf
9. Algorri M, Wang T, McQueen JX, Cauchon N. Considerations for a decentralized manufacturing paradigm. Pharmaceutical Engineering. September/October 2023. Accessed April 11, 2025. https://ispe.org/pharmaceutical-engineering/september-october-2023/considerations-decentralized-manufacturing
10. Ghosh S. Are plant-based APIs the future of pharma and nutraceuticals? Pharmaceutical Online. January 29, 2025. Accessed April 11, 2025. https://www.pharmaceuticalonline.com/doc/are-plant-based-apis-the-future-of-pharma-and-nutraceuticals-0001

10. US Centers for Disease Control. Antimicrobial resistance facts and stats. November 12, 2024. Accessed April 11, 2024. https://www.cdc.gov/antimicrobial-resistance/data-research/facts-stats/index.html
11. Pandey AK, Cohn J, Nampoothiri V, Gadde U, Ghataure A, Kakkar AK, Gupta YK, Malhotra S, Mbamalu O, Mendelson M, Märtson AG, Singh S, Tängdén T, Shafiq N, Charani E. A systematic review of antibiotic drug shortages and the strategies employed for managing these shortages. Clin Microbiol Infect. 2025 Mar;31(3):345-353. doi: 10.1016/j.cmi.2024.09.023.
12. Bonet OS, Sasangohar F. Investigating the Food and Drug Administration biotherapeutics review and approval Process: Narrative review. JMIR Form Res. 2021;5(3):e14563. Published 2021 Mar 4. doi:10.2196/14563

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In Conversation

DR. TARUNJOT SINGH

"In a world of rapid innovation, staying grounded in empathy and ethics will define the future leaders of healthcare"

Director ,
Safety and Pharmacovigilance, United Kingdom &
Honorary Global Vice President,
SCRMP

Q: Dr. Tarun, tell us about your professional journey. What drew you to Pharmacovigilance?

A: After completing my dental degree, I realized how critical drug safety is to public health. Pharmacovigilance offered a dynamic, high impact space where clinical expertise, data interpretation, and policy converge.

Q: Beyond drug safety, what trends in healthcare excite you?

A: Precision medicine, digital therapeutics, AI-driven diagnostics, and wearable health technology are transforming patient care. Integrating patient-reported outcomes and real-world data into decision-making is the next frontier.

Q: Share a leadership experience that shaped your approach.

A: Leading a multicultural team during a complex regulatory project taught me the importance of empathy, cultural sensitivity, and empowerment. It reaffirmed my belief in servant leadership.

Q: How do you maintain personal wellbeing amidst high-pressure roles?

A: Mindfulness routines, exercise, reading, and spending quality time with family. Setting boundaries and unplugging is essential in today's hyper-connected world.

Q: One piece of advice for future healthcare professionals?

A: Stay adaptable and embrace interdisciplinary learning. The healthcare industry demands professionals who are curious, ethical, and digitally fluent.

Q: What excites you about your role as Vice President of the society?

A: Mentorship programs, driving innovation-led dialogues, and building a future-ready, compassionate community. I see this society as a platform blending tradition with technology.

Interviewed By
Gayoor Khan, Gen Secretary, SCRMP

- Nikhil C Bhanumathi

PHARMA 2025: BREAKTHROUGHS, DISRUPTIONS, AND THE ROAD AHEAD

The pharmaceutical industry stands at a pivotal moment of transformation in 2025, with breakthrough technologies and evolving market dynamics creating unprecedented opportunities alongside complex challenges. AI-driven innovations, precision medicine, and digital health solutions are revolutionizing how drugs are discovered, developed, and delivered to patients. By 2025, artificial intelligence is expected to drive 30% of new drug discoveries, significantly cutting costs and accelerating the development of personalized treatments [1]. The convergence of these technological advancements with changing regulatory frameworks and market pressures demands strategic foresight from industry leaders. This article explores the key trends shaping the pharmaceutical landscape, analyses emerging regulatory and market dynamics, and provides actionable insights for pharmaceutical executives navigating this rapidly evolving ecosystem.

Key Trends in Pharmaceutical Innovation

Precision Medicine & Personalized Therapies

The precision medicine revolution is fundamentally changing treatment paradigms and reshaping pharmaceutical R&D strategies. The global precision medicine market was valued at USD 103.81 billion in 2024 and is projected to reach approximately USD 464.26 billion by 2034, representing a robust compound annual growth rate (CAGR) of 16.15% [2]. This remarkable growth trajectory underscores the industry's shift toward more targeted, personalized approaches to treatment.

The momentum behind personalized medicine is evident in regulatory approvals. Personalized medicines topped one-third of new U.S. Food and Drug Administration (FDA) drug approvals for the fourth consecutive year in 2023 [3]. This trend is particularly pronounced in the rare disease space, where the number of new personalized treatment approvals more than doubled in 2023, with the FDA approving 16 new personalized treatments for rare diseases compared to just six in 2022 [3].

Advancements in genomics and biotechnology are key drivers of this transformation. Precision medicine leverages these advances, along with data analytics, to achieve more accurate disease diagnosis, better prediction of potential risks, and selection of relevant treatments that improve patient outcomes while minimizing adverse effects [2]. Leading pharmaceutical companies are increasingly incorporating biomarkers and genetic profiling into their R&D pipelines, facilitating more targeted therapeutic approaches.

As precision medicine continues to evolve, we can expect further integration of multi-omics data, expanded use of companion diagnostics, and more sophisticated patient stratification approaches to drive the next generation of personalized therapies.

AI and Data Analytics in Drug Discovery

Artificial intelligence is revolutionizing pharmaceutical R&D, particularly in early-stage drug discovery. By 2025, it is estimated that 30% of new drugs will be discovered using AI, which has been shown to reduce drug discovery timelines and costs by 25-50% in preclinical

stages [1]. This transformative capability allows pharmaceutical companies to identify successful therapies earlier and shift resources away from candidates unlikely to succeed.

Industry experts predict that 2025 will see a surge in silico discovery and autonomous AI scientific assistants, reducing the need for human involvement in traditionally hands-on research workflows [4]. This shift is being driven by a focus on training AI models with complex, scientifically relevant datasets and the development of agent AI that scientists can task with objectives using natural language and interactive dialogs [4]. Through these natural language interfaces, researchers can more easily leverage AI to accelerate target and candidate identification, making early research faster, more efficient, and more effective.

AI is not merely another tool for data analysis; it holds the potential to completely transform the drug discovery and development process [1]. The technology's ability to process vast amounts of biomedical data, identify patterns, and generate insights is creating new possibilities for innovation across the pharmaceutical value chain. Importantly, AI will not replace employees but will augment human abilities, prioritizing both intellectual capabilities (IQ) and emotional intelligence (EQ) [1]

To fully capitalize on AI's potential, pharmaceutical companies need to foster a culture of openness, continuous learning, and willingness to adopt new ways of working [1]. Success requires that people trust the data, change their decision patterns, and act with urgency and speed. What industry leaders call "snackable AI" – AI used in day-to-day work – needs to be adopted at scale to improve decision-making across organizations [1]

Digital Health and Telemedicine

The convergence of digital technology and healthcare has given rise to revolutionary concepts in healthcare delivery, with digital health and tele-pharmacy standing at the forefront of this transformation. Digital health encompasses a wide range of technologies and services, including telemedicine, remote monitoring, mobile health applications, electronic health records, and wearable devices, all aimed at enhancing healthcare delivery [5].

Within this broader ecosystem, tele-pharmacy has emerged as a vital component specifically focused on providing pharmaceutical services remotely [5]. Tele-pharmacy enables patients to consult with pharmacists through video conferencing, phone calls, or secure messaging platforms, allowing pharmacists to provide medication counselling, answer questions, and address concerns related to prescriptions, over-the-counter medications, and potential drug interactions [5].

This digital transformation offers numerous advantages, especially for individuals in underserved or rural areas where access to pharmacy services may be limited5. By 2025, telehealth, wearables, and home care solutions are expected to give patients more control over their health while simultaneously reducing environmental impact [1].

- Nikhil C Bhanumathi

The integration of digital health technologies into pharmaceutical business models is creating new opportunities for patient engagement, medication adherence, and real-world data collection. Pharmaceutical companies are increasingly partnering with digital health platforms to enhance their offerings and create more comprehensive healthcare solutions. As these technologies continue to evolve, we can expect to see more seamless integration between traditional pharmaceutical products and digital therapeutics, creating new value propositions for patients, providers, and payers.

Regulatory and Market Dynamics

Global Regulatory Harmonization

The pharmaceutical industry operates in an increasingly globalized environment, where the need for harmonized regulatory approaches has become more critical than ever. Global regulatory harmonization aims to align technical requirements for drug development and evaluation across different regions, streamlining processes and improving efficiency [6].

Regulatory harmonization has evolved significantly over time, from disparate systems where individual countries worked independently to strengthen their regulatory capacities to increasing levels of collaboration today6. Modern harmonization efforts range from collaboration on selected topics to Mutual Recognition Agreements (MRAs) and even full integration in cases like the European Union [6].

These efforts can be categorized into three main types: bilateral agreements between two countries or between one country and a group of countries; regional initiatives involving multiple countries within a specific geographic region (e.g., European Union, Pan-American Network for Drug Regulatory Harmonization); and global initiatives led by international organizations like the World Health Organization (WHO) and the International Council for Harmonisation (ICH) [6].

The benefits of harmonization for pharmaceutical companies include more efficient regulatory processes, reduced duplication of efforts, faster time to market, and broader global access. As harmonization efforts continue to progress, pharmaceutical companies will need to stay informed about evolving requirements and adapt their regulatory strategies accordingly to maximize the advantages offered by more streamlined global regulations.

Implementation of EU Joint Clinical Assessment

One major change in 2025 is the start of a new EU law called the EU HTA Regulation (EU Regulation 2021/2282), which began on January 12, 2025. This law affects cancer treatments and advanced therapy medicines (ATMPs). This marks a big change in how health technology assessments (HTAs) are done in Europe. Now, companies must work more closely across different teams and make sure they follow specific evidence requirements and PICO (Population, Intervention, Comparator, Outcome) guidelines [7]. The new Joint Clinical Assessment (JCA) process looks a lot like the older EUnetHTA evaluations but brings more work, especially for smaller drug companies that may not have enough

- Nikhil C Bhanumathi

resources. Experts think 2025 will be a year full of uncertainty, as companies figure out how to handle the new JCA process. The first JCA report is expected in November 2025, and everyone will be watching to see how each country uses this information in their own health decisions.

Escalating Medical Costs and Pricing Pressures

In 2025, the global healthcare system is facing a serious affordability crisis due to rising costs driven by structural issues and inflation [8]. Medical expenses are expected to rise by 10.4% on average worldwide, continuing the double-digit growth trend seen since 2023. The Asia-Pacific region leads with a 12.3% increase, largely because of India's sharp 13% surge [9]—the highest among major economies. North America is seeing an 8.7% increase due to high spending on GLP-1 drugs and a rebound in postponed care, while behavioural health claims are rising at 15% annually [10]. The Middle East and Africa are experiencing the fastest cost acceleration, going from 10.4% to 12.1%, while Europe's increase is slower at 9.4%. Since 2022, global healthcare costs have grown by 23%, outpacing general inflation by 4.8 times in developing countries. Several key pressure points are contributing to this trend. First, new drugs like biologics and GLP-1 agonists are responsible for 38% of cost growth among insured populations. While these therapies improve outcomes, they also raise sustainability concerns—55% of insurers in the Middle East and Africa identify drug innovation as the top cost driver. In the U.S., the Inflation Reduction Act may lower Medicare costs temporarily, but could reduce investment in chronic disease treatment research. Second, countries like India are facing a mismatch between healthcare infrastructure and patient access. Although costs are rising by 13%, 71% of people still find care unaffordable, and 36% of insured patients skip treatment due to high out-of-pocket expenses. This reflects a 40% shortfall in hospital beds and a 65% shortage of specialist doctors [9].

Mental health care is another growing cost burden, now accounting for 48% of global medical cost increases. In Europe, mental health disorders are rising 70% faster than physical conditions, and insurers expect these costs to grow by 15% each year through 2027 [11]. To help manage rising expenses, biosimilars are projected to save up to $380 billion globally by 2025, but current usage only offsets 12% of drug price inflation. Telehealth is gaining traction, especially in the Middle East and Africa, where 58% of insurers now offer virtual care. Early results show a 22% drop in non-emergency ER visits. In Europe, 75% of insurers blame rising costs on weakening public healthcare systems. In response, 38 countries now require mandatory reporting on the return on investment from health technology assessments (HTA) to guide better spending. Looking ahead to 2026, without major reforms, the global ratio of medical costs to GDP could reach 11.3%. Key developments to watch include how EU HTA regulations affect drug pricing, whether India's digital health investments can scale effectively, and the release of WHO's mental health cost-control guidelines expected in Q3 2025. As demographic changes, new treatments, and post-pandemic care needs collide, the world is entering a "new abnormal" in healthcare economics. While innovations like AI diagnostics—projected to reach 19% adoption by 2026—offer some hope, truly solving the affordability crisis will require rethinking insurance models and accelerating the shift to value-based care.

- Nikhil C Bhanumathi

Strategic Considerations for Pharma Leaders

Strategic Collaborations & Partnerships

The dawn of 2025 marks a pivotal moment in the pharmaceutical industry, providing great opportunities alongside significant challenges [1]. While the industry faces obstacles such as looming patent cliffs, R&D budget pressures, and shifting product landscapes, strategic activity and partnerships represent a key area for progress [1].

Biopharma mergers and acquisitions (M&A) have shown robust performance in 2024, with momentum expected to continue into 2025 [1]. This M&A activity, along with funding growth, is projected to boost innovation, expand pipelines, and accelerate treatment availability [1].

Strategic collaborations between pharmaceutical companies, technology firms, and biotech start-ups are becoming increasingly important for driving innovation and maintaining competitive advantage. These partnerships allow companies to access complementary capabilities, share risks, and accelerate development timelines in an industry where speed to market can be a critical differentiator.

As AI and other advanced technologies become more integral to pharmaceutical R&D, partnerships with technology companies and academic institutions will be critical for accessing specialized expertise and capabilities. Pharmaceutical executives should develop clear partnership strategies that align with their overall business objectives, carefully evaluate potential partners, and establish effective governance structures to manage collaborative relationships.

Innovative Financing Models

The current pharmaceutical innovation financing framework in the United States rests on the notion of a defined period of marketing exclusivity combined with the expectation of reimbursement for clinically valuable, cost-effective therapies [12]. However, evolving market dynamics and increasing development costs are driving interest in alternative financing approaches.

Emerging financing models include venture philanthropy, public-private partnerships, risk-sharing agreements, and outcomes-based contracts. These approaches aim to distribute risk more effectively across stakeholders, align incentives with patient outcomes, and ensure sustainable funding for innovative therapies in an era of increasing cost pressures.

For pharmaceutical leaders, understanding and leveraging these new financing models will be essential for supporting continued innovation, particularly in high-risk therapeutic areas or for addressing unmet medical needs in smaller patient populations. Companies should assess which financing approaches best align with their portfolio strategy and develop expertise in structuring and implementing these arrangements to maximize both financial sustainability and therapeutic impact.

- Nikhil C Bhanumathi

Patient-Centric Innovation

Patient-centered approaches are becoming increasingly important across the pharmaceutical value chain, from R&D to commercialization. By focusing on patient needs and preferences, pharmaceutical companies can develop more targeted therapies, design more effective clinical trials, and create more compelling value propositions for healthcare systems.

The rise of precision medicine exemplifies this patient-centric approach, with therapies increasingly tailored to specific patient characteristics. In 2023, personalized medicines accounted for over one-third of new FDA drug approvals for the fourth consecutive year, with particularly strong growth in the rare disease space [3].

To successfully implement patient-centric strategies, pharmaceutical companies need to engage patients throughout the product lifecycle, leverage real-world data to understand patient experiences and outcomes, and develop comprehensive support programs that address the full spectrum of patient needs. Companies that excel at patient-centricity will be better positioned to create meaningful innovations and differentiate their offerings in increasingly competitive markets where patient voice and choice are becoming more influential factors.

References

1. World Economic Forum, "https://www.weforum.org/stories/2025/01/2025-can-be-a-pivotal-year-of-progress-for-pharma/," World Economic Forum, 16 Jan 2025.
2. Cervicon Consulting, "https://www.cervicornconsulting.com/precision-medicine-market," Cervicon Consulting, 12 Mar 2025.
3. P. M. Coalition, Personalized Medicine Coalition, 29 Feb 2024.
4. "https://www.ddw-online.com/tech-ml-and-ai-industry-predictions-for-2025-33318-202501/," CDD Vault, 20 Jan 2025.
5. "https://iimtu.edu.in/blog/digital-health-and-telepharmacy-transforming-healthcare-delivery/," 21 Jun 2024.
6. "https://www.freyrsolutions.com/blog/navigating-the-complexities-of-global-regulatory-harmonization-in-pharma," Freyr Solutions, 24 Mar 2025.
7. "https://remapconsulting.com/hta/pricing-and-market-access-trends-2025/," 08 Jan 2025. [Online].
8. "https://healthcareasiamagazine.com/healthcare/news/global-medical-costs-stay-elevated-in-2025-report".
9. "https://www.financialexpress.com/business/healthcare/indias-healthcare-costs-to-rise-13-in-2025-beat-global-average-report/3800929/," [Online].
10. "https://www.pwc.com/us/en/industries/health-industries/library/behind-the-numbers.html".
11. "https://www.statista.com/outlook/hmo/mental-health/europe".
12. D. C. e. all, "https://pmc.ncbi.nlm.nih.gov/articles/PMC7247916/," 26 May 2020.
13. "https://www.srgtalent.com/blog/how-to-overcome-the-top-4-pharma-supply-chain-challenges," 11 Aug 2024.
14. "https://www.resourcefulfinancepro.com/news/healthcare-2025/".
15. "https://healthcareasiamagazine.com/healthcare/news/global-medical-costs-stay-elevated-in-2025-report".

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- Deepak Kumar

DRUG SAFETY IN THE DIGITAL AGE: HOW REAL-WORLD EVIDENCE IS CHANGING THE GAME

A New Era of Pharmacovigilance Is Here

Medicine is no longer limited to the confines of hospitals and clinics in the era of smartphones, wearable technology, and AI-powered health applications. Drug safety monitoring is changing as a result of the same digital revolution that changed how we place restaurant orders and call a cab.

Clinical trials have been the gold standard for assessing a drug's safety and effectiveness for many years. The problem is that, although these studies are great at demonstrating how a medication functions in controlled settings, they frequently fail to capture what occurs when the medicine is used in the messy, unpredictable world of daily life.

Welcome to the digital era of pharmacovigilance, where clinical research and Real-World Evidence (RWE) are combining to make medication safer, smarter, and more individualized than it has ever been.

⚠ The Old Model: Why It's No Longer Enough

Imagine selling a new automobile to individuals who would drive it through busy cities, mountain roads, and streets full of potholes after testing it on a flawless, deserted highway. In essence, that is what conventional clinical studies do. They conduct drug tests in meticulously regulated settings with stringent guidelines regarding who is permitted to participate.

Because of this, it is frequently uncertain what uncommon side effects, long-term consequences, and how the medicine functions in people with other health conditions will occur until hundreds, if not millions, of people begin using it. From the discontinuation of rofecoxib (Vioxx) to post-market safety warnings on commonly used drugs, history has demonstrated that this gap may have potentially fatal outcomes.

- Deepak Kumar

What Is Real-World Evidence, and Why Should You Care?

Information on how pharmaceuticals function in the actual world is known as "real-world evidence." It is collected from wearable technology, insurance claims, patient registries, electronic health records (EHRs), and even social networking sites.

This data repository provides information that clinical studies are unable to:

- How does a blood pressure drug affect elderly patients with diabetes?
- Are there unexpected side effects when a cancer drug is combined with another therapy?
- Do patients actually adhere to a medication' prescribed dosage outside of trial settings?

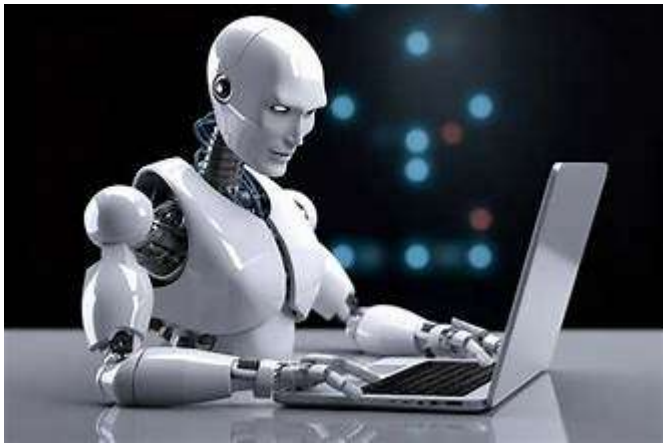
Thanks to cutting-edge AI tools, researchers can now sift through these massive data sets to detect early warning signs, track long-term outcomes, and personalize treatment plans.

AI, Wearables & Social Media: The New Pharmacovigilance Toolkit

Wearable technology, such as smartwatches, has made it possible to monitor health continuously in recent years. These gadgets record blood sugar levels, heart rates, and sleep patterns continuously.

Real-time analysis of this data by AI-powered software can identify possible problems before a patient is aware that something is amiss.

In the meantime, social media has become a surprising yet effective instrument for pharmacovigilance. Long before side effects or pharmaceutical experiences are officially documented, patients frequently post about them online. Healthcare practitioners can keep ahead of the curve and address issues before they become more serious by mining this data.



How Clinical Trials Are Evolving Too

Digitalization is even being applied to clinical trials. The emergence of Decentralized Clinical Trials (DCTs) enables participants to employ home delivery services, smartphone apps, and telemedicine for study pharmaceuticals, facilitating participation from a variety of backgrounds and producing real-world data in addition to controlled research.

- Deepak Kumar

RWE is becoming more and more integrated into the decision-making procedures of regulatory bodies such as the FDA and EMA. Actually, RWE has already backed new medicine approvals and label expansions in a number of instances.

The Road Ahead: Challenges and Possibilities

Despite its great potential, this digital revolution is not without its challenges. It is necessary to address concerns like data privacy, record standardization, and the moral application of AI.

Furthermore, updating legal frameworks, clear data-sharing agreements, and international cooperation are necessary for combining insights from disparate sources.

However, the objective is clear: a future in which every prescription is based on the results of millions of individuals, just like you and me, rather than merely what succeeded in a trial with 500 carefully chosen volunteers.

Final Thought: Medicine That Learns From Us

A new sort of medicine has emerged as a result of the digital era, one that learns from patients in addition to treating them. Healthcare might become safer, quicker, and more inclusive by combining the accuracy of clinical studies with the wealth of real-world data. It is our responsibility as medical professionals and aspiring pharmacists to welcome these advancements and make sure that technology strengthens rather than undermines the sacred relationship that exists between a doctor, patient, and medication.

Quick Facts: Real-World Evidence at a Glance

- Over 60% of clinical trials today incorporate some form of digital health technology.
- FDA' RWE Framework (2018) opened the doors for real-world data in regulatory decisions.
- Top sources of RWD: Electronic health records, insurance claims, mobile health apps, wearable devices, and social media.

References

1. Sherman RE, et al. Real-World Evidence —What Is It and What Can It Tell Us? N Engl J Med. 2016;375(23):2293–297. https://doi.org/10.1056/NEJMsb1609216
2. Makady A, et al. What Is Real-World Data? A Review of Definitions Based on Literature and Stakeholder Interviews. Value Health. 2017;20(7):858–65. https://doi.org/10.1016/j.jval.2017.03.008
3. Corrigan-Curay J, et al. Real-World Evidence and Real-World Data for Evaluating Drug Safety and Effectiveness. JAMA. 2018;320(9):867–68. https://doi.org/10.1001/jama.2018.10136
4. FDA. Framework for FDA' Real-World Evidence Program. December 2018. Available at: https://www.fda.gov/media/120060/download
5. Casey JA, et al. Using Electronic Health Records for Population Health Research: A Review of Methods and Applications. Annu Rev Public Health. 2016;37:61–1. https://doi.org/10.1146/annurev-publhealth-032315-021353
6. Botsis T, et al. Secondary Use of EHR: Data Quality Issues and Informatics Opportunities. Summit Transl Bioinform. 2010;2010:1–.
7. Schneeweiss S. Learning from Big Health Care Data. N Engl J Med. 2014;370(23):2161–163. https://doi.org/10.1056/NEJMp1401111
8. Ciani O, et al. Time to Review the Role of Real-World Evidence in Healthcare Decision Making. PharmacoEconomics. 2021;39(11):1279–289. https://doi.org/10.1007/s40273-021-01073-5
9. Eichler HG, et al. From Adaptive Licensing to Adaptive Pathways: Delivering a Flexible Life-Span Approach to Bring New Drugs to Patients. Clin Pharmacol Ther. 2015;97(3):234–46. https://doi.org/10.1002/cpt.59

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- Morziul Haque & Ms. Anchal Chhabra

AI DRIVEN SAFETY EVALUATION: FROM TRIALS TO TRUTHS

Evolution of Drug Safety Monitoring

The journey of drug safety monitoring has evolved from informal observational reporting to structured, data-driven systems. Initially, adverse drug reactions (ADRs) were often discovered only after widespread use, sometimes with devastating consequences such as the thalidomide tragedy. This led to the development of formal pharmacovigilance frameworks and regulatory oversight. Spontaneous reporting systems like the FDA Adverse Event Reporting System (FAERS) were introduced to capture these ADRs. However, these systems were limited by issues such as underreporting, bias, and delayed detection of rare events [1].

To address these limitations, real-world data sources such as electronic health records (EHRs), insurance claims, and patient registries began to play a larger role. These data pools provided a broader and more dynamic understanding of drug performance in diverse populations. Recent advancements have enabled the integration of big data analytics into safety monitoring, allowing for earlier detection of potential risks and improving public health response times [2]. This shift from passive to active surveillance, and from manual review to algorithmic detection, marks a pivotal evolution in pharmacovigilance.

Gaps in the conventional drug safety evaluation process have been observed as a result of drug withdrawals from the market in recent years. Rofecoxib, Lysergic acid diethylamide (LSD), Benfluorex, Sibutramine, Pergolide, Pemoline, Valdecoxib, Levamisole, Hydromorphone hydrochloride extended release (Palladone), Cisapride, Drotrecogin alfa, Aprotinin, and many more are among the medications that have been withdrawn following post-market surveillance. These medications are used for a variety of indications, including rheumatoid arthritis, hallucinations, hyperlipidemia, weight loss, Parkinson's disease symptoms, attention deficit hyperactivity disorder (ADHD), sedative, arthritis, immunomodulatory, narcotic analgesic, heartburn, anti-thrombotic, and antifibrinolytic respectively. All of this, points to a flaw in our clinical trial procedures that necessitates the incorporation of cutting-edge AI systems in order to prevent these economical losses to healthcare management worldwide [1].

Role of AI in Future Raising Drug Safety

In the context of future drug safety issues, artificial intelligence (AI) has been introduced to provide a more accurate and economical assessment. For this various case studies have been published which involves the evaluation of a deep learning model to assess drug-induced liver injury (DeepDILI) in accordance with real-world scenarios. Assessing whether knowledge from previously approved drugs could be used to predict the DILI potential of newly approved drugs was the goal of the DeepDILI assessment. For this real-world scenario was mimicked so to check prediction capability of the tool for newer drugs to launch into the market. The above case study thus suggests that artificial intelligence (AI)

can help overcome the gap between the current limitations of post-marketing surveillance and the conventional system of drug safety evaluation [3]. Furthermore, a number of other case studies about AI-enabled software being used to track negative events associated with different real-world scenarios have been published. One of these is the COVID-19 case, which involves using a variety of advanced techniques to identify pulmonary adverse events linked to hypertensive drugs. These were documented to demonstrate its improved capacity for monitoring drug safety. Additionally, SPINEL is another AI-enabled program that is used to identify known side effects associated with opioids. Various tools are also implemented in clinical trials to increase the efficiency of overall developmental process. Hence, it is clear that early in the drug development stage, natural language processing (NLP) must be integrated in order to obtain the information required for drug safety [2]. Conclusively, in order to keep up with the complexity of healthcare, the future of drug safety rests in blending the development of AI tools with human expertise to guarantee the precise and early detection of a given drug's adverse drug reactions [4].

Human-AI Collaboration in Drug Safety

Artificial intelligence (AI) has significantly enhanced the efficiency of pharmacovigilance by enabling real-time analysis of complex health datasets. From mining electronic health records (EHRs) to monitoring adverse events on social platforms, AI systems are capable of detecting safety signals at a speed and scale previously unattainable. However, AI systems operate without clinical intuition, often lacking the ability to contextualize or prioritize risks [5].

Human experts provide the critical lens needed to interpret these AI-generated findings. Pharmacovigilance professionals can determine whether a flagged signal is clinically significant or simply a data artifact. Their insights help refine AI outputs and prevent inappropriate actions based on false positives. Moreover, human oversight is vital to addressing ethical concerns, such as algorithmic bias and the need for transparency in decision-making processes. As the demand for explainable AI grows, regulatory authorities now stress the importance of maintaining human involvement to ensure that technology remains accountable and aligned with patient safety goals [6]. This collaborative approach, blending AI's data processing power with human judgment, forms a robust model for the future of drug safety monitoring.

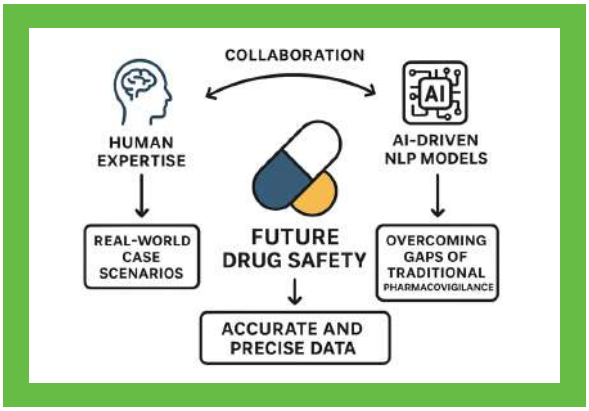

Fig. Illustration of Human-AI collaboration overcoming gaps and raising future drug safety.

References

1. Alomar M, Palaian S, Al-Tabakha MM. Pharmacovigilance in perspective: drug withdrawals, data mining and policy implications. F1000Research. 2019 Dec 16;8:2109.
2. Kumar RK, Velusamy S. Harnessing Artificial Intelligence for Enhanced Pharmacovigilance: A Comprehensive Review. Indian Journal of Pharmacy Practice. 2025 Apr;18(2):171-9.
3. Connor S, Li T, Roberts R, Thakkar S, Liu Z, Tong W. Adaptability of AI for safety evaluation in regulatory science: A case study of drug-induced liver injury. Frontiers in artificial intelligence. 2022 Nov 8;5:1034631.
4. Oluwaseyi, Joseph & Enoch, Olanite. (2024). AI and Pharmacovigilance: Enhancing Drug Safety Monitoring.
5. Shortliffe EH, Sepúlveda MJ. Clinical decision support in the era of artificial intelligence. Jama. 2018 Dec 4;320(21):2199-200.
6. Heaven D. Why deep-learning AIs are so easy to fool. Nature. 2019 Oct 1;574(7777):163-6

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- Dr. Hitesh Bharucha

ROLE OF DECENTRALIZED TRIALS FOR NEWER DRUG APPROVALS

Decentralized clinical trials (DCTs) refer to a model of conducting clinical trials where aspects of the study are conducted outside of the traditional clinical research sites. Instead, patients participate in the trial from their homes, local clinics, or hospitals, and data is collected remotely using technology.

Decentralized trials offer several benefits over traditional clinical trials. One of the key advantages is that they can increase patient participation and diversity in clinical trials. This is because they allow patients who may not be able to travel to clinical research sites to participate in studies. Additionally, DCTs can provide more convenient and flexible options for patients, which may help increase patient retention and adherence to the study protocol.

Another benefit of DCTs is that they can improve the speed and efficiency of clinical trial execution. By reducing the need for patients to travel to clinical research sites and eliminating the need for on-site monitoring, DCTs can help reduce the time and cost associated with traditional clinical trials.

Furthermore, DCTs have been particularly useful during the COVID-19 pandemic, as they allow for continued clinical trial activity while minimizing the risk of exposure to the virus.
For newer drug approvals, DCTs may provide a faster, more efficient pathway to approval. By increasing patient participation and reducing trial timelines, DCTs may allow for faster collection and analysis of data, which could ultimately accelerate the drug development process. Additionally, by allowing for more diverse patient populations to participate in trials, DCTs may help ensure that new drugs are safe and effective for a broader range of patients.
Overall, decentralized trials are an increasingly important component of the clinical trial landscape and have the potential to significantly improve the drug development process, leading to faster approvals of new drugs.

There are several examples of decentralized clinical trials (DCTs) that have been used in the launch of new drugs.

Examples:

1. Verkada: In 2020, Verkada launched a DCT to study a new drug for the treatment of non-alcoholic steatohepatitis (NASH). The trial enrolled patients remotely and used a virtual platform to collect patient-reported outcomes and other data.

2. Roche: In 2021, Roche announced a DCT for a new drug to treat spinal muscular atrophy (SMA). The trial uses at-home monitoring devices to collect patient data, and patients can participate remotely without having to travel to a clinical research site.

- Dr. Hitesh Bharucha

3. Novartis: In 2020, Novartis launched a DCT to study a new drug for the treatment of multiple sclerosis (MS). The trial used a virtual platform to collect patient data, and patients could participate remotely from their homes.

4. Pfizer: In 2021, Pfizer announced a DCT for a new drug to treat breast cancer. The trial used a decentralized approach to allow patients to participate remotely and collected data using wearable devices and other remote monitoring technologies.

5. Eli Lilly: In 2020, Eli Lilly launched a DCT to study a new drug for the treatment of migraine headaches. The trial used a virtual platform to enroll patients and collect data, and patients could participate from their homes.

These are just a few examples of how DCTs are being used in the launch of new drugs. As the use of remote technologies continues to expand, we can expect to see more DCTs in the future.

Decentralized clinical trials (DCTs) have been increasingly utilized in recent years as a way to modernize the clinical trial process and improve patient access to clinical research. The following are some potential benefits and drawbacks of using DCTs in new drug approvals:

Benefits:

1. Improved patient access: DCTs can increase patient participation by reducing the burden of travel and allowing patients to participate from the comfort of their own homes.
2. Increased efficiency: DCTs can be conducted more efficiently, with faster enrollment and reduced study timelines. This can help accelerate the drug approval process and bring new treatments to patients more quickly.
3. More diverse patient populations: DCTs can enable participation from a more diverse patient population, as patients from rural or remote areas can participate without the need to travel long distances.
4. Enhanced data collection: DCTs can use electronic data capture and remote monitoring technologies, which can improve data quality and reduce errors associated with manual data entry.

Drawbacks:

1. Regulatory challenges: DCTs may raise regulatory challenges related to data privacy, data security, and patient safety, which must be carefully addressed.
2. Limited oversight: DCTs can be conducted remotely, which may limit the ability of investigators and regulators to oversee study conduct and ensure protocol compliance.
3. Technological barriers: DCTs require access to technology, which may limit participation from certain patient populations, such as those who do not have access to the internet or who are not comfortable using technology.

- Dr. Hitesh Bharucha

4. Lack of face-to-face interaction: DCTs may lack face-to-face interaction between patients and healthcare providers, which can be important in building trust and rapport.

Health Authorities perspective for Decentralized Clinical Trials –

Health authorities, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have generally been supportive of decentralized clinical trials (DCTs) as a way to modernize the clinical trial process and improve patient access to clinical research.

The FDA issued guidance in September 2020 titled "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency," which includes recommendations for decentralized approaches to clinical trials. The guidance highlights the importance of ensuring patient safety, maintaining data integrity, and preserving the reliability of trial results in the context of DCTs.

Similarly, the EMA has acknowledged the potential benefits of DCTs, such as reduced burden on patients and increased efficiency of trial conduct. In 2020, the agency issued a reflection paper on the use of remote and decentralized approaches in clinical trials, which outlines key considerations for sponsors and investigators when designing and conducting DCTs.

However, health authorities have also emphasized the importance of ensuring that DCTs meet regulatory requirements for data quality, patient safety, and ethical considerations. They have called for careful planning and risk mitigation strategies to address potential challenges such as ensuring adequate oversight and monitoring of study conduct, ensuring data privacy and security, and addressing potential disparities in access to technology among patient populations.

In summary, health authorities generally support the use of DCTs as a way to improve patient access to clinical research and modernize the clinical trial process, but also emphasize the importance of ensuring regulatory compliance and addressing potential challenges associated with DCTs

Decentralized Clinical Trials India Context –

The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for pharmaceuticals and medical devices in India. CDSCO has recognized the potential benefits of decentralized clinical trials (DCTs) and has been supportive of their use in India.

- Dr. Hitesh Bharucha

In March 2020, CDSCO issued guidance on the conduct of clinical trials during the COVID-19 pandemic, which included recommendations for remote and virtual trial conduct. The guidance acknowledged that DCTs could be an effective way to continue clinical research during the pandemic while minimizing risks to participants and trial staff.

CDSCO has also indicated a willingness to work with sponsors and investigators to facilitate the use of DCTs in India. In a webinar held in June 2020, CDSCO officials emphasized the need for DCTs to meet ethical and regulatory requirements, but also expressed a willingness to explore new approaches to clinical trial conduct in light of the pandemic.

In addition, CDSCO has taken steps to facilitate the use of technology in clinical trials, such as allowing electronic signatures and e-submissions for regulatory documents. The organization has also established a digital platform, Sugam, for online submission of clinical trial applications and related documents.

Overall, CDSCO has recognized the potential benefits of DCTs and has indicated a willingness to work with sponsors and investigators to facilitate their use in India, while also emphasizing the importance of meeting ethical and regulatory requirements

There have been several decentralized clinical trials (DCTs) conducted in India in recent years, particularly in response to the COVID-19 pandemic.

Examples:

1. The Indian Council of Medical Research (ICMR) conducted a multicenter, randomized controlled trial comparing two treatments for COVID-19 in hospitalized patients using a DCT approach. The trial used remote monitoring and electronic data capture to collect study data, and investigators used telemedicine to communicate with study participants.

2. A clinical trial investigating the safety and efficacy of a novel oral anticoagulant in patients with deep vein thrombosis was conducted using a DCT approach. The trial used remote monitoring and electronic data capture to collect study data, and participants received study medication and conducted study visits at home.

3. A Phase III trial investigating the safety and efficacy of a new tuberculosis drug regimen was conducted using a hybrid DCT approach. The trial used a combination of in-person and remote visits, and investigators used electronic data capture and mobile health technology to collect study data.

4. A DCT was conducted to investigate the safety and efficacy of a new oral hypoglycemic agent for the treatment of type 2 diabetes. The trial used remote monitoring and electronic data capture to collect study data, and participants received study medication and conducted study visits at home.

- Dr. Hitesh Bharucha

These examples demonstrate the feasibility and potential benefits of DCTs in India, particularly in the context of the COVID-19 pandemic and the need for alternative approaches to clinical trial conduct.

Conclusion

While DCTs have potential benefits such as improved patient access and increased efficiency, there are also potential challenges related to regulatory oversight, technological barriers, and lack of face-to-face interaction. These factors must be carefully considered when designing and conducting DCTs for new drug approvals.

References:

https://www.veeva.com/blog/delivering-on-the-promise-of-digital-trials-simplified-experiences-for-sites-and-patients
https://www.nap.edu/read/12879/chapter/4
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-015-1107-1
https://www.actrials.com/the-clinical-trial-process-impending-changes-in-the-regulatory-framework/
https://climedo.de/en/blog/decentralized-clinical-trials-as-a-key-step-into-the-future/
https://medium.com/elektra-labs/decentralized-clinical-trials-f12fffb72610

Dr. Hitesh Bharucha

PROFILE:

Dr. Hitesh Bharucha is an accomplished clinical research professional with over 18 years of experience across global pharmaceutical and CRO environments. Currently serving as Associate Director –RWE-HEOR at EVERSANA APAC, he spearheads project delivery and business development for Real-World Evidence and Health Economics Outcomes Research initiatives. His expertise spans the execution of RWE, observational, and diagnostic studies across APAC and EU regions, offering deep operational insights that streamline clinical startup and data collection. Prior to EVERSANA, he held key roles at renowned organizations including Pfizer, Roche, Novartis, and IQVIA, contributing to clinical operations, vendor management, and regulatory compliance. Dr. Bharucha holds a Ph.D. in Pharmacy Practice, a B. Pharm, PGDCR, and an MBA.

- Dr.Payal Gajbhiye

FROM STATUS UPDATES TO DRUG UPDATES: SOCIAL MEDIA'S CRITICAL MISSION IN PHARMACOVIGILANCE

In the ever-changing landscape of healthcare and pharmaceutical safety, a new player has emerged, reshaping the way we approach drug safety monitoring. Social media, once considered merely a platform for personal connections and entertainment, has become an invaluable tool in the field of pharmacovigilance. This article explores the significant impact of social media on drug safety monitoring, its benefits, challenges, and the future implications for the pharmaceutical industry and patient care.

Pharmacovigilance, the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, has traditionally relied on formal reporting systems and clinical trials. However, the advent of social media has opened up new avenues for real-time, large-scale data collection and analysis, fundamentally altering the landscape of drug safety monitoring.

Experts in the field of pharmacovigilance have noted that social media platforms provide an unprecedented volume of real-world data. Patients are sharing their experiences with medications openly and in real-time, offering insights that might not be captured through traditional reporting methods.

Indeed, the sheer scale of social media usage presents a unique opportunity for pharmacovigilance. With billions of active users across various platforms, social media offers a vast pool of potential data. Patients discuss their medications, side effects, and overall experiences with treatments on forums, in Facebook groups, and through tweets. This wealth of information, when properly analyzed, can provide early signals of adverse drug reactions (ADRs) that might not be immediately apparent in clinical trials or formal reporting systems.

One of the key advantages of social media in pharmacovigilance is its ability to detect safety signals rapidly. Traditional methods of ADR reporting often involve a time lag between the occurrence of an adverse event and its reporting to regulatory authorities. Social media, on the other hand, allows for near-instantaneous sharing of experiences. This real-time nature of social media data can potentially lead to faster identification of safety issues, enabling quicker responses from pharmaceutical companies and regulatory bodies.

Healthcare analytics specialists emphasize the power of this approach. By applying advanced natural language processing and machine learning algorithms to social media data, patterns and potential safety signals can be identified much earlier than traditional methods allow. This could potentially save lives by enabling faster interventions when serious adverse events are detected.

However, the use of social media in pharmacovigilance is not without its challenges. One of the primary concerns is the quality and reliability of the data. Unlike formal ADR reports,

social media posts are unstructured and often lack crucial details such as dosage information or concurrent medications. Moreover, the informal nature of social media communication can make it difficult to distinguish between genuine ADRs and unrelated complaints or misinformation.

Privacy concerns also present a significant hurdle. While many social media users share health information publicly, there are ethical considerations around using this data for pharmacovigilance purposes. Striking a balance between leveraging valuable health insights and respecting individual privacy remains a key challenge for the industry.

Despite these challenges, the potential benefits of integrating social media into pharmacovigilance practices are too significant to ignore. Many pharmaceutical companies and regulatory agencies are already incorporating social media monitoring into their drug safety strategies.

The FDA, for instance, has launched initiatives to explore the use of social media in pharmacovigilance. Their "Sentinel" program aims to proactively monitor the safety of medical products using electronic health data from multiple sources, including social media. Similarly, the European Medicines Agency (EMA) has recognized the potential of social media in their pharmacovigilance activities and is working on guidelines for its appropriate use.

Regulatory affairs experts point out that regulatory bodies are increasingly recognizing the value of social media data in pharmacovigilance. However, they're also acutely aware of the need for standardized approaches to ensure the quality and reliability of this data. It's likely that more concrete guidelines and regulations in this area will emerge in the coming years.

The integration of social media into pharmacovigilance practices is not just changing how we detect ADRs; it's also transforming the relationship between pharmaceutical companies and patients. Social media platforms offer an opportunity for direct engagement with patients, allowing companies to disseminate important safety information quickly and widely.

Moreover, social media is playing a crucial role in patient education and empowerment. Online communities and forums provide spaces for patients to share experiences, ask questions, and learn from each other. This peer-to-peer information sharing can lead to better-informed patients who are more likely to recognize and report potential ADRs.

Looking to the future, the role of social media in pharmacovigilance is set to expand further. As artificial intelligence and machine learning technologies continue to advance, our ability to extract meaningful insights from the vast amount of unstructured social media data will improve. This could lead to more accurate and timely detection of safety signals, ultimately enhancing patient safety.

The rise of wearable technology and health apps presents another exciting frontier for

social media pharmacovigilance. These devices generate a wealth of real-time health data that, when combined with social media insights, could provide a more comprehensive picture of a drug's safety profile in real-world use.

Industry leaders envision a future where pharmacovigilance becomes a truly collaborative effort between healthcare providers, pharmaceutical companies, regulatory bodies, and patients. Social media will play a crucial role in facilitating this collaboration, enabling real-time sharing of safety information and fostering a culture of open communication about drug safety.

However, as we move towards this future, it's crucial to address the challenges and limitations of social media pharmacovigilance. Developing robust methodologies for data validation, ensuring patient privacy, and establishing clear regulatory guidelines will be essential steps in fully realizing the potential of social media in drug safety monitoring.

Conclusion

Social media has emerged as a powerful tool in the pharmacovigilance arsenal, offering unprecedented access to real-world data and enabling faster detection of potential safety issues. While challenges remain, the integration of social media into pharmacovigilance practices represents a significant step forward in our ability to monitor and ensure drug safety.

As we continue to navigate this evolving landscape, it's clear that social media will play an increasingly important role in shaping the future of pharmacovigilance. By embracing these new technologies and methodologies, while carefully addressing the associated challenges, we can work towards a future where adverse drug reactions are detected and addressed more quickly and effectively, ultimately leading to safer medications and better patient outcomes.

The role of social media in pharmacovigilance is not just a trend; it's a paradigm shift that promises to revolutionize how we approach drug safety in the 21st century. As the field continues to evolve, it will be fascinating to see how this powerful tool is further integrated into pharmacovigilance practices, potentially ushering in a new era of patient safety and personalized medicine.

- Dr.Payal Gajbhiye

Dr. Payal Gajbhiye

PROFILE:

Dr. Payal Gajbhiye is a distinguished Pharmaceutical Physician at Parexel, bringing over a decade of unparalleled expertise to the forefront of pharmaceutical safety. With more than 12 years of hands-on experience spanning pharmacovigilance, clinical trials, and clinical practice, Dr. Gajbhiye stands as a beacon of knowledge and innovation in the field. She serves on the editorial board of the esteemed Journal of Pharmacovigilance and Drug Research (JPADR) and board member of the Society of Clinical Research and Medical Professionals (SCRMP) where her insights shape the discourse on critical safety issues in the pharmaceutical industry. Her commitment to advancing the field is evident in her active participation in various professional groups. Her passion for nurturing talent has led her to become a sought-after mentor, dedicated to shaping the next generation of professionals in the pharmaceutical and healthcare sectors.

In Conversation

GURPREET SINGH

Vice President, Managing Director *Integrated Safety at IQVIA United Kingdom &* ***Honorary Global President*** *of SCRMP*

"Leadership is less about authority and more about empathy, resilience, and clarity of purpose."

Q: Gurpreet, thank you for joining us. What inspired you to pursue a career in Pharmacovigilance and life sciences?

A: I've always had a deep interest in healthcare and its direct impact on lives. The evolving regulatory landscape and the opportunity to contribute to patient safety kept me engaged. It's a unique field where science, ethics, and public health intersect and that's deeply motivating.

Q: What motivated you to take up the role of President for this society?

A: The need for a collaborative, forward-thinking platform for clinical research professionals was long overdue. This society offers a space to exchange ideas, foster professional growth, and prepare the next generation of healthcare leaders.

Q: Technology is reshaping our industry. What excites you most about digital healthcare?

A: AI, machine learning, and real-world data analytics are revolutionizing how we manage clinical trials, Pharmacovigilance, and patient care. From predictive models to decentralized trials, technology is driving efficiency and accuracy, but ethical governance is key.

Q: What has been your most defining leadership lesson?

A: Enabling others to succeed. Leadership is about creating environments where people feel empowered, valued, and inspired to deliver their best.

Q: Any hobbies or activities you turn to for balance?

A: Running, reading non-fiction particularly leadership and business. It helps me recharge and stay grounded.

Q: A final message for our members

A: Stay curious, keep learning, and challenge conventional thinking. The future belongs to those who embrace change and lead with integrity.

Interviewed By
Gayoor Khan, Gen Secretary, SCRMP

- Prisha Naidu

THE FUTURE OF DRUG SAFETY: FROM CLINICAL TRIALS TO REAL WORLD EVIDENCE

Real-world evidence (RWE) is quickly emerging as an essential element in healthcare decision-making, supplementing conventional clinical trial evidence. Randomized controlled trials (RCTs) are commonly accepted as the best way to determine the efficacy and safety of medical interventions. RWE can validate and reinforce the findings obtained from conventional RCTs. RWE is based on real-world data (RWD). Clinicians need to understand RWE in order to inform treatment choices, evaluate the efficacy of treatments, and track drug safety in larger patient groups.

Real-world evidence (RWE) remains in the spotlight globally with increased utilization in enabling regulatory decision-making for biologics and drugs. Therefore, regulatory authorities worldwide have continued to issue various guidance documents on RWE. Nonetheless, utilization of RWE in regulatory decision-making regarding effectiveness remains an evolving space, where despite guidance, there still remains a role for experience from precedents and pilots in shaping best practices.

That nations utilizing RWE for the purpose of making regulatory decisions regarding drugs and biologics were moving toward a stepwise process for the development of the subsequent 3 key regulatory components: (a) regulatory RWE frameworks, (b) RWD quality guidance, and (c) real-world study methods guidance (Figure 1). With recent RWE guidance documents published up to January 2023 we have continued to see this trend. Several key regulatory bodies have now moved on from the earlier published initial frameworks or position papers to issuing fully detailed practical guidance documents on RWE for use in regulatory decision-making.

The majority of these guidance documents cover data quality and standards (Figure 2). Regulatory bodies have also started releasing guidance on study methodology for various real-world study designs (Figure 2). In addition, there are a few guidance documents focused on the procedural aspects of engaging with regulatory agencies to discuss RWE and submit documents containing RWD/E (Figures 1, 2).

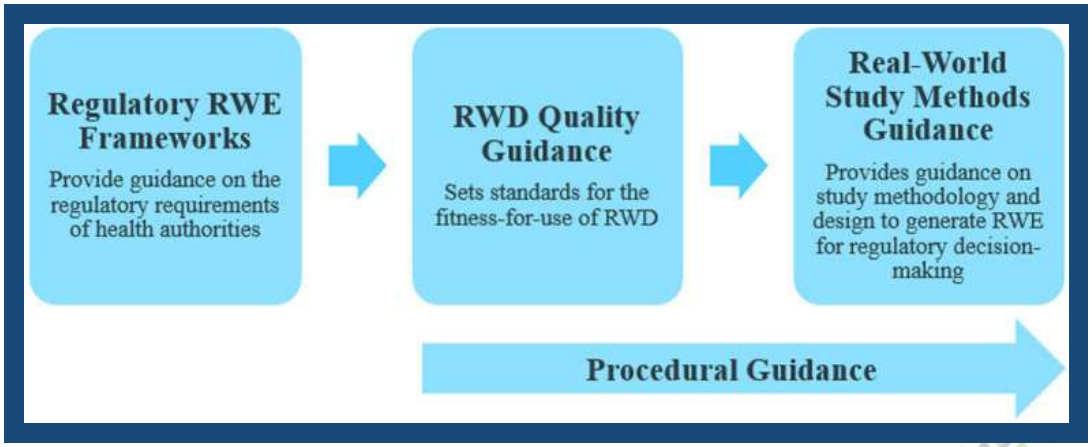

Figure 1

- Prisha Naidu

In general, how far the aforementioned stepwise criteria have advanced (i.e., with some countries simply taking existing frameworks and using them rather than creating their own) reflects how far along the RWE environment is and how practical it would be to base such decisions on evidence like that in a given area.

Figure 2

Real-world evidence (RWE) is clinical proof of a medical product's safety and effectiveness created through the use of real-world data (RWD) from routine healthcare delivery.
Knowledge of patient clinical course is an important doorway to the design of successful clinical trials and ultimately to the ability to bring treatments to those in need.
Real-world evidence (RWE) is medical proof created in the course of routine patient treatment.
There are several sources of RWE, such as patient health records, pharmacy claims, registries, and social media.

Healthcare Databases

Healthcare databases are collections of data applied to record general clinical and lab data in their day-to-day practice. Healthcare databases, like EHRs, are most likely the strongest sources of RWD. EHR data can further assist in dealing with many safety issues, particularly long-term safety data, frequently not caught over a short period of III- and IV-Phase studies. The databases are not designed for research purposes but can be redirected to assist RWE studies, providing insights into the effectiveness of treatment, safety, healthcare utilization, and outcome in real-world environments.

- Prisha Naidu

Registries

Registries are structured collections that gather, examine, and release observational data on a population of patients having certain characteristics prospectively. Data from registries are typically obtained in the format of cohort studies with a definite clinical or public health-related intention. Registries have progressed from paper patient records to electronic databases and may hold extensive amounts of data, including a range of information, such as clinical data or biological samples archived in bio-banks. Registries can be population-based or hospital based. For instance British Society for Rheumatology. National Cancer Registration and Analysis Service (NCRAS) is an England population-based cancer registry, which is a unit of Public Health England (PHE). American Academy of Orthopedic Surgeons (AAOS) registry programme is a hospital-based programme of registry, which works with the motive to enhance orthopedic care through collection and analysis of patient information to provide better outcomes.

Claims Databases

Claims databases consist of billing and other healthcare administrative information entered by health insurers, or by pharmacies. Type of healthcare database holding administrative billing data produced when healthcare providers file claims with payers (insurance companies, government programs) for reimbursement. Claims databases are an important resource for RWE because they are large in size, have standardized format, and longitudinally track patient interactions with the healthcare system. It captures real-world, routine care, large populations for rare disease analysis it also monitors treatment patterns, adherence, costs, and healthcare resource utilization and appropriate for comparative effectiveness, safety, and HEOR studies.

Other Sources such as social media

Social media are increasingly being noticed in recent times as a source of patient data. There are websites and apps where users can network amongst themselves to create and share content. Social networking sites can be useful in offering patient insights regarding different health issues, including adverse events, reasons for changing treatment and non-compliance, and quality of life. Patients tend to go to social media to seek information about their illnesses, get connected to fellow patients, share experiences, and seek social support. Patient-powered research networks (PPRNs) constitute another source of RWD. These are patient- and patient partner-designed and operated web platforms, for example, patient advocacy/support groups, patient-run organizations, and other stakeholders like carers/guardians, clinicians, and researchers.

- Prisha Naidu

How is RWE Derived from RWD -

Experimental and observational study designs of varying types can be utilized to derive RWE from RWD.

The various categories of RWE studies include non-interventional (i.e., observational) studies, registry analysis, claims database analysis, patient surveys, and abstraction and analysis. Observational studies may be in the form of cohort studies, cross-sectional studies, or case-ontrol studies. The data for RWE studies may be collected prospectively or retrospectively. Often, some prospective, multicentre, observational studies are conducted as part of routine clinical practice, and such trials are called pragmatic clinical trials. Cohort Studies

Cohort studies aim to assess the incidence, etiology and risk factors, natural history of disease, disease prognosis, and treatment outcomes. They can be retrospective, involving a post hoc analysis of accumulated data. Alternatively, they can be prospective.

Cross-Sectional Studies

Cross-sectional studies seek to measure disease prevalence and outcomes, where they take into account a single group of patients at once with concurrently compared treatment and outcomes. The study design has been applied to provide insights into the prevalence of underdosing or optimal dose selection among real-world populations.

Case-Control Studies

Case-control investigations are most commonly carried out in a retrospective pattern, that is, they will first detect the cases, that is, individuals with an ailment, then retrospectively compare the causally related factors. They can compare a single end result and cause, and prove useful in situations of rare illness or lengthy incubation period of the disease.

Registry Analysis

Registry analyses yield information regarding individual patient populations and are typically retrospective in design based on prospectively accrued data.

Claims and EHR Database Studies

Claims database research are generally retrospective, longitudinal, and cross-sectional data analyses of healthcare and administrative database data, including treatment and clinical data, diagnosis codes, and hospital admission and discharge data. Claims database research are generally designed to examine healthcare resource consumption (HCRU) and expenditures. Electronic health records database research are retrospective, observational data analyses of medical records and charts that were designed to evaluate clinical treatments and outcomes.

Conclusion

Evidence studies from the real world have been employed to investigate various dimensions in disease and health, including epidemiology, disease burden, treatment patterns, safety, treatment outcomes, long-term outcomes, and patient-reported

outcomes like satisfaction, quality of life, medication adherence, and patient experience.

They can also offer useful information regarding the economic dimension of a medical product. It can lead to less time being spent on trials and saving costs if applied in the initial phases of drug development. It can also significantly enhance the evidence drawn from RCTs, therefore completing gaps left by previous clinical knowledge. Similarly, because of the evaluation of different records revealed that drugs are experiencing another MOA and revealed that in RWE. It has been long recognized that RCTs alone cannot provide an overall view of safety of any medicinal product, and unreported adverse effects encountered during RCTs are commonly seen in everyday clinical practice. This is the reasoning behind the regulatory agencies requiring the manufacturer to obtain safety-related data post-marketing approval in the form of Phase IV or post-marketing surveillance (PMS) studies, which are essentially RWE studies.

Furthermore, EHRs and patient-generated sources (e.g., social media platforms or PPRNs) are more difficult to analyze compared to the structured data. However, they are more expressive in the sense that they can possibly reveal more raw information about unforeseen side effects of medical products. For example, information from social media platforms were utilized in pharmacovigilance in a 2019 paper on the identification of cutaneous adverse drug reactions to anticancer drugs approximately seven months prior to when they were released in the literature. This research also presented new side effects that had not been reported before. Recently, RWE is being used more and more to inform clinical and regulatory decisions such as approval of medical products. Historically, the regulatory decisions for new drug approvals have always been made based on RCT results. Recently, there are many instances where RWE was used to make regulatory decisions around new drug approvals, supplemental approvals, and to inform label updates. In March 2017, the USFDA utilized RWE evidence in the form of historical control arm to provide marketing approval of avelumab for the treatment of Merkel cell carcinoma, the first use of RWE for initial drug approvals.

References

1. Dang A. Real-World Evidence: A Primer. Pharmaceut Med. 2023 Jan;37(1):25-36. Doi: 10.1007/s40290-022-00456-6. Epub 2023 Jan 5. PMID: 36604368; PMCID: PMC9815890.
2. Cook SF, Rhodes T, Schlusser C, Han S, Chen C, Zach N, Murthy V, Davé S. A Descriptive Review of Global Real World Evidence Efforts to Advance Drug Discovery and Clinical Development in Amyotrophic Lateral Sclerosis. Front Neurol. 2021 Nov 8;12:770001. Doi: 10.3389/fneur.2021.770001. PMID: 34819914; PMCID: PMC8606522.
3. Trailokya AA, Srivastava A, Mukaddam Q, Suryawanshi S, Chaudhry S, Kulkarni S. Real-world Evidence Simplified for Clinicians. J Assoc Physicians India. 2025 Feb;73(2):78-80. Doi: 10.59556/japi.73.0839. PMID: 39928003.
4. Burns L, Le Roux N, Kalesnik-Orszulak R, Christian J, Dudinak J, Rockhold F, Khozin S, O'onnell J. Real-world evidence for regulatory decision-making: updated guidance from around the world. Front Med (Lausanne). 2023 Oct 30;10:1236462. Doi: 10.3389/fmed.2023.1236462. PMID: 38020096; PMCID: PMC10643567.

- Prisha Naidu

Prisha Naidu

PROFILE:

Prisha Naidu is a Pharm.D student and Clinical Pharmacologist Intern at Manipal Hospitals, Pune, with rich experience across top hospitals like Apollo and Sahyadri. She currently serves as National Joint Secretary at SCRMP and holds international certifications in mental health counseling. Passionate about both clinical care and psychology, she aims to bridge medicine and empathy for better patient outcomes.

- Sneha Choudhury

HASHTAGS & HEADACHES: SOCIAL MEDIA IN MODERN PHARMACOVIGILANCE

Introduction

A patient tweets: "his new antidepressant is giving me the worst headaches!!!"While it might be just a random post for others , but to Data scientists and researchers, it could be an early sign of a serious adverse drug reaction.

Because information travels so quickly now, and people around the world communicate more easily, we have access to many different medicines. People also expect these medicines to be very safe. To handle these new challenges, we need to plan carefully and look at the whole picture. We need constant progress in all areas of drug safety to make sure medicines are safe and improve public health. It would be helpful to have a new worldwide system for sharing information about the good and bad effects of medicines.[1]

Thinking of "big data" in drug safety as looking at lots and lots of information online to find out if there are any unexpected problems when people take medicines. Instead of just relying on doctors and patients reporting issues, this approach uses computer programs to automatically search through different online sources like:

- Reports of bad reactions to drugs: These are official reports people make when they think a medicine caused a problem.
- Medical research papers: Scientific articles that might mention side effects of drugs.Electronic medical records: Digital health information from hospitals and clinics.
- Social media: What people are saying about their medicines online.

By looking at all this data together, computers can help the Food and Drug Administration (FDA) and other groups keep a closer eye on how safe medicines are and make better decisions.[2]

Definition

According to the World Health Organisation (WHO), Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". [3]

Traditional pharmacovigilance refers to the methods used to monitor the safety of medicines, especially after they have been approved for use and are available in the market. It refers to the methodical way of collecting data , assessing the risks and taking steps to avoid adverse drug reactions (ADRs). This includes reviewing published scientific literature, managing spontaneous reports from healthcare professionals and patients, and conducting post-marketing safety studies.

- Sneha Choudhury

Whereas, Modern pharmacovigilance refers to the wisdom and conditioning relating to the identification, evaluation, understanding, and forestallment of negative goods or any other drug- related issues, that has been significantly impacted by the rise of social media.

Theoretical Background

These days, there is a huge amount of information online from social media, phone apps, and websites. This means we need special computer methods, called "data mining," to make sense of it all. This report explains how using new technologies, along with the regular methods can help us spot harmful side effects from medicines sooner. This is important for keeping people safe when they take drugs.We looked carefully at lots of research papers and inventions related to drug safety. We searched big online libraries like PubMed and Google Scholar for articles about this topic. A project in Europe called WEB-RADR is looking at using phone apps and social media to report bad drug effects. It is important for the computer programs that do the "data mining" to pick out only the useful information. This helps us to guess what hazard might happen more faster and correctly . Two common ways to do this are called the "frequentist" and "Bayesian" approaches.Checking for bad drug reactions even before a drug is available to the public can help us spot problems early in its development. After a drug is on the market, it is important to keep track of safety reports and information from hospitals, doctors' offices, and people reporting side effects themselves. We can do this by looking at electronic health records and other databases.[4]

Original perspective or analysis

Keeping an eye on diseases is super important for figuring out when outbreaks might happen and how to stop them. Usually, we do this by looking at information from hospitals and health departments
–things like who is getting sick, who is dying, lab results, and surveys. Doctors and hospitals collect this stuff. Then computers came along and made it easier to see this information and share it faster. But now, with the internet and smartphones, it is a whole different ballgame! Not only can we get the usual health info quicker, but people are also sharing information themselves online, often on websites and apps that are not even about health in the first place.[5,6]

Here's a breakdown of the significance of social media in modern pharmacovigilance practices :

Opportunities and Advantages:

- Real-time Data Gathering: Social media platforms provide a continuous stream of data directly from patients and healthcare providers, allowing for the near real-time monitoring and reporting of suspected adverse drug reactions (ADRs). This can lead to earlier discovery of implicit safety issues than traditional reporting methods.
- Increased Reach and Awareness: Social media helps more people, including doctors and nurses, learn about possible side effects from medications. This makes everyone more likely to report any problems they notice and pay closer attention to drug safety.
- Patient-Centric Approach: By providing a space for patients to share their medication

- Sneha Choudhury

experiences in their own terms, social media can yield rich insights into how drugs are used, the side effects that have been experienced and the treatment outcomes from the patient's viewpoint, & thereby promoting a more patient-centric approach to drug safety.

- Data Diversity: Because social media connects a wide range of people across different locations, it allows for the collection of drug reaction information from demographically and geographically diverse groups, often missed by standard drug safety monitoring.
- Passive Surveillance: In contrast to traditional reporting, which depends on individuals actively submitting information, social media enables a passive monitoring method by capturing the unsolicited comments and opinions of a wider and more varied group of people.
- Early Signal Detection: Social media provides a potential access for pharmacovigilance to detect adverse drug reaction signals because patients may first, or exclusively, discuss their symptoms or side effects in online conversations, bypassing traditional reporting channels.
- Risk Communication: Social media enables direct engagement with patients and healthcare professionals, facilitating the timely delivery of accurate medicinal product safety information, addressing concerns, and spreading crucial safety messages and risk communication.
- Understanding Patient Language and Context: By analyzing social media data, we can gain a deeper understanding of patients' medication experiences as they describe them, including the everyday language and non-medical terms they use for side effects, which can provide valuable insights into adverse drug reactions (ADRs).

Challenges and Limitations:

- Lack of Standardization: The absence of standardized methodologies for gathering and analyzing social media data presents a significant hurdle to incorporating it effectively into our established routine drug safety monitoring . This inconsistency retards our ability to systematically identify and understand potential safety concerns raised on these platforms.
- Data Quality and Reliability: Without proper medical context and given the potential for inaccurate information, it is a significant hurdle to determine causality between a drug and an event mentioned on social media.
- Privacy Concerns: Pharmacovigilance monitoring of social media raises worries about the privacy of individuals whose health information might be collected and utilized.
- Noise and Irrelevance: Most social media data is not related to drug safety, which makes it hard to find the information that is actually beneficial for pharmacovigilance.
- Difficulty in Identifying Individuals: A significant barrier in addressing social media reports of adverse events is the difficulty in verifying the reporter, & thereby impeding any attempts at follow-up or more thorough examination.
- Spontaneous and Informal Language: Automated analysis of social media texts using natural language processing is challenging because of its informal style, which often includes abbreviations, slangs, and grammatical errors.
- Potential for Bias: Biased information from media outlets and online communities can shape social media conversations, leading to biased perceptions of drug safety.

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Modern Approaches:

Despite challenges , modern pharmacovigilance is increasingly leveraging social media data by:

- Developing sophisticated tools and techniques: By applying Natural Language Processing(NLP) and Artificial Intelligence(AI), researchers are analyzing significant social media data to precisely determine potential adverse drug reactions (ADRs) and emerging patterns.
- Establishing guidelines and best practices: Together, regulatory agencies and the pharmaceutical industry are aspiring to create ethical and effective approaches for using social media in pharmacovigilance.
- Combining social media data with traditional data sources: By bringing together social media insights with data from adverse event reports, Electronic Health Records (EHRs), and other sources, we can gain a much richer understanding of drug safety
- Engaging with patients online: Patient feedback and support are being actively examined by some organisations through social media engagement and they provide support to those patients as well.

Conclusion

While social media alone cannot take the place of strong systems of traditional pharmacovigilance, it positively serves as a powerful extra tool in today' digital age. When seemlessly merged with data from wearable health devices and advanced powerful big data analytics, social media offers real-time insights that enhance our understanding of drug safety. By working with this combined approach, the future of drug safety could become more anticipatory , patient-centered, and responsive –eventually resulting in better detection of adverse drug reactions and improved public health outcomes. In a hyper-connected world, drug safety might just go viral- that spreads like wildfire, leading to positive outcomes.

References:

1) V. Kumar: Challenges and future considerations for pharmacovigilance. J Pharmacovigilance, 1 (1) (2013), pp. 1-3.
https://scholar.google.com/scholar_lookup?title=Challenges%20and%20future%20considerations%20for%20pharmacovigilance&publication_year=2013&author=V.%20Kumar
2) CL Ventola: Big Data and Pharmacovigilance: Data Mining for Adverse Drug Events and Interactions - Pharmacy and therapeutics, 2018.
https://pmc.ncbi.nlm.nih.gov/articles/PMC5969211/
3) Pharmacovigilance WHO -Regulation and Prequalification.
https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance
4) Mandali V. Satwika, Dudala S. Sushma, Varun Jaiswal, Syed Asha and Tarun Pal:The Role of Advanced Technologies Supplemented with Traditional Methods in Pharmacovigilance Sciences - Recent Patents on Biotechnology, Volume 15, Issue 1, Mar 2021, p. 34 – 50.
https://www.benthamdirect.com/content/journals/biot/10.2174/1872208314666201021162704
5) Salathé M, Bengtsson L, Bodnar TJet al.. Digital epidemiology. PLoS Comput Biol 2012;8:e1002616.
https://scholar.google.com/scholar_lookup?title=Digital%20epidemiology&author=M%20Salath%C3%A9&author=L%20Bengtsson&author=TJ%20Bodnar&publication_year=2012&journal=PLoS%20Comput%20Biol&volume=8&pages=e1002616
6) Salathé M, Freifeld CC, Mekaru SR, Tomasulo AF, Brownstein JS. Influenza A (H7N9) and the importance of digital epidemiology. N Eng J Med 2013; 369:401-4.
https://scholar.google.com/scholar_lookup?title=Influenza%20A%20%28H7N9%29%20and%20the%20importance%20of%20digital%20epidemiology&author=M%20Salath%C3%A9&author=CC%20Freifeld&author=SR%20Mekaru&author=AF%20Tomasulo&author=JS%20Brownstein&publication_year=2013&journal=N%20Eng%20J%20Med&volume=369&pages=401-4

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ABOUT THE AUTHOR:

Sneha Choudhury is an aspiring Doctor of Pharmacy, from UIPS, Chandigarh University and the Director of Outreach at the Central Executibe Committee of SCRMP. She is building a strong foundation in pharmaceutical sciences and clinical practice. Her academic journey has sparked a deep interest in drug therapy, patient care, and evidence-based research. She is passionate about contributing to the advancement of healthcare through scientific writing, research participation, and continuous learning. As an aspiring clinical pharmacist, She aims to bridge the gap between research and patient outcomes in the healthcare system.

SCRMP IN ASSOCIATION WITH MEDICAPS UNIVERSITY INDORE MADHYA PRADESH ON 23RD AUGUST 2025

The Faculty of Pharmacy is organizing an International Conference on "The Future of Drug Safety: From Clinical Trials to Real-World Evidence," in collaboration with Society of Clinical Research and Medical Professionals on 23 Aug 2025.

Message from the Chancellor

It is with immense pride and anticipation that I extend my greetings to everyone gathered for the International Conference on "The Future of Drug Safety: From Clinical Trials to Real-World Evidence." This significant event, spearheaded by our esteemed Faculty of Pharmacy in partnership with SCRMP, truly embodies the spirit of innovation and societal commitment that defines Medicaps University.

As Chancellor, I witness daily the dedication of our academic community to not only impart knowledge but also to contribute meaningfully to critical global challenges. The theme of this conference resonates deeply with our university's vision of fostering research and education that directly impacts human well-being. Drug safety is not merely a regulatory concern; it is a fundamental pillar of public health and trust, demanding continuous vigilance, scientific rigor, and ethical foresight.

This conference serves as a vital nexus, bringing together brilliant minds from diverse backgrounds –researchers, clinicians, policymakers, and industry leaders. It is through such collaborative platforms that we can bridge the gap between groundbreaking scientific discoveries and their safe, effective application in the real world. The transition from controlled clinical trials to the complexities of real-world evidence presents both challenges and unparalleled opportunities for enhancing patient outcomes.

I commend the Faculty of Pharmacy for their foresight in organizing this timely and relevant conference, and I extend my sincere appreciation to SCRMP for their invaluable collaboration. May your discussions be vibrant, your insights profound, and your collective efforts pave the way for a healthier and safer future for all.

My best wishes for a highly successful and impactful conference.

Shri R.C Mittal
Chancellor
Medicaps University

Message from the Vice-Chancellor

It gives me immense pleasure to extend a warm welcome to all participants, esteemed speakers, and delegates who attending the International Conference on "The Future of Drug Safety: From Clinical Trials to Real-World Evidence." This crucial event, organized by the Faculty of Pharmacy, Medicaps University, in collaboration with SCRMP, marks a significant milestone in our collective pursuit of safer and more effective healthcare solutions.

In today's rapidly evolving pharmaceutical landscape, the importance of robust drug safety protocols cannot be overstated. From the rigorous stages of clinical trials to the invaluable insights gleaned from real-world evidence, every step plays a vital role in ensuring patient well-being and public trust. This conference provides a timely and essential platform for leading experts, researchers, and professionals to converge, share knowledge, and deliberate on the innovative approaches that will shape the future of pharmacovigilance.

Medicaps University is committed to fostering an environment of academic excellence and impactful research. The Faculty of Pharmacy, with its dedication to cutting-edge education and research, is perfectly positioned to lead discussions on such a pertinent topic. Our collaboration with SCRMP further strengthens the reach and impact of this conference, bringing together diverse perspectives and expertise.

I am confident that the discussions will be highly enriching, leading to new collaborations, groundbreaking ideas, and actionable strategies that will ultimately enhance global drug safety practices. I encourage all participants to engage actively, share their insights, and make the most of this exceptional opportunity.

My best wishes for a successful and productive conference.

Dr. (Prof) Dilip K Patnaik
Vice-Chancellor
Medicaps University

Message from the Dean

It brings me great pleasure and a deep sense of pride that I welcome you all to the International Conference on "The Future of Drug Safety: From Clinical Trials to Real-World Evidence." This conference, a foundation event for our department this year, is a testament to the dedication and hard work of every individual involved, and I am particularly thrilled that we are organizing it in collaboration with SCRMP.

As the Dean of the Faculty of Pharmacy, I am acutely aware of the critical role our profession plays in safeguarding public health. The journey of a drug, from its inception in a lab to its widespread use, is complex and fraught with challenges. Ensuring its safety at every stage is not just a scientific imperative but a moral obligation. This conference's theme directly addresses the evolving landscape of drug safety, highlighting the indispensable bridge between the controlled environment of clinical trials and the dynamic, diverse realities of real-world evidence.

We've designed this conference to be a vibrant forum for knowledge exchange, robust discussions, and the forging of new collaborations. It's an opportunity for us all—tudents, researchers, academics, and industry partners—o delve into cutting-edge research, share best practices, and collectively shape the future of Pharmacovigilance. I am confident that the insights gained and connections made here will significantly contribute to advancing drug safety globally.

I extend my heartfelt gratitude to the organizing committee for their tireless efforts, to our collaborators at SCRMP, and to all our distinguished speakers and delegates for their participation. Let's make this conference a truly memorable and impactful event.

Dr. Sanjay Jain
Dean
Faculty of Pharmacy
Medicaps University

Message from Dr. Hemant Khambete
- Convenor of the Conference

It gives me immense pleasure to welcome all participants to the International Conference on "he Future of Drug Safety: From Clinical Trials to Real-World Evidence". This conference is a step forward in our shared commitment to advancing patient safety and fostering innovation in pharmacovigilance. The collaboration between the Faculty of Pharmacy, Medicaps University, and SCRMP brings together academic excellence, industry expertise, and a global perspective. I am confident that this platform will encourage meaningful discussions, promote research collaborations, and inspire actionable solutions for the future of drug safety. I wish the conference great success and look forward to engaging with all our esteemed speakers and delegates.

Dr. Hemant Khambete
Head of Department &
Convenor of the Conference,
Faculty of Pharmacy, Medicaps University
National Vice President,
Faculty Forum (Pharmacy Wing), SCRMP

Message from Dr. Sumeet Prachand
- Organising Secretary

As Organising Secretary, I am delighted to be part of an event that unites brilliant minds from academia, industry, and regulatory bodies. Drug safety is not just a professional obligation—t is a shared responsibility that directly impacts global health outcomes. Through this conference, we aim to address emerging challenges, explore innovative tools, and bridge the gap between clinical trials and real-world evidence. I extend my gratitude to all contributors, participants, and partners for making this initiative possible. Together, we can shape a safer and healthier future.

Dr. Sumeet Prachand
Faculty of Pharmacy,
Medicaps University

Message from Prof. Ritu Sapra
Co- Organising Secretary

It is a privilege to extend a warm welcome to all our esteemed delegates, speakers, and participants at this International Conference on "he Future of Drug Safety: From Clinical Trials to Real-World Evidence". This conference is a testament to our collective dedication towards advancing pharmacovigilance practices and ensuring patient safety. I am confident that the exchange of ideas, research, and experiences here will foster innovative approaches and strengthen collaborations across academia, industry, and regulatory sectors. Let us work together to translate knowledge into meaningful action for the benefit of global healthcare. My heartfelt wishes for the resounding success of this event.

Prof. Ritu Sapra
Faculty of Pharmacy,
Medicaps University,
National Joint Secretary,
Pharmacy Faculty Forum SCRMP

Message from our President

It is with immense pleasure and a deep sense of honour that I address this distinguished gathering at the conference. As the Global President of SCRMP, I am truly delighted to be among so many passionate and brilliant minds. Clinical research, as we all know, is far more than just a profession; it is a profound and noble mission. It is a commitment we make to the global community to relentlessly advance the frontiers of medicine, to uphold the highest standards of patient safety and protection, and, most importantly, to bring hope to countless individuals and families facing health challenges.

The work we do is crucial, and it is a testament to our collective dedication to improving human health. Our shared learnings at this conference are not just about exchanging data and findings; they are about fostering innovative thinking that challenges the status quo and forges stronger collaborations across disciplines, institutions, and borders. By working together, we can overcome complex challenges, accelerate the development of new therapies, and ensure that our research has a tangible, positive impact on a healthier future for all. May our time here inspire new ideas, strengthen our professional bonds, and reinforce our shared purpose in this vital endeavour.

Mr. Gurpreet Singh

Vice President,

Managing Director Integrated Safety, IQVIA, UK

Honorary Global President, SCRMP

Message from our Vice President

It is with great pride and enthusiasm that I welcome you all to the first international conference of the Society for Clinical Research and Medical Professionals (SCRMP) in the vibrant city of Indore, India. This event marks a significant milestone in our journey to foster global collaboration, innovation, and excellence in clinical research and healthcare. I extend my heartfelt gratitude to all participants, speakers, and partners for being part of this momentous occasion. Together, let us shape the future of medical science and professional growth.

Dr. Tarunjot Singh
Director at Syenos health UK
Honorary Global President, Vice President, SCRMP

Message from Punam Kumari

It is with great pleasure and a sense of profound responsibility that I stand before you today. Clinical research, as we all know, is the very bedrock of medical progress, and it is a privilege to contribute to this vital field. Our work is not merely about data and trials; it is about the unwavering pursuit of knowledge that can save lives and improve health outcomes for people around the world.

This conference is a testament to our shared dedication, and it serves as a valuable and dynamic forum for us to connect, to exchange critical insights, and to explore the cutting-edge innovations that are shaping the future of healthcare. It is a place where we can reaffirm our collective commitment to ethical, patient-centered research— principle that must always guide our endeavours. As we engage in these important discussions and share our findings, I wish all participants continued inspiration and success. May our collaborative efforts here ignite new ideas and propel us forward in our shared mission of shaping a healthier, more hopeful future for all.

Punam Kumari
PV Consultant, Clinexel, UK

Message from Dr. Shipra Sehgal

It's an honour to be part of this conference on "he Future of Drug Safety: From Clinical Trials to Real World Evidence."The clinical research landscape is rapidly evolving, with digital transformation redefining how trials are designed, conducted, and evaluated. Emerging technologies such as AI, real-world data analytics, and decentralized trial models are accelerating drug development while enhancing patient engagement and data quality. As the industry embraces innovation, collaboration across stakeholders becomes even more vital to ensure meaningful and ethical progress. This is a transformative era for clinical research, and I applaud the organizers for bringing these critical discussions to the forefront.

Dr. Shipra Sehgal
PV Consultant, Clinexel, UK

Message from Dr.Himanshu Bhatnagar

From clinical trials to post marketing surveillance, pharmacovigilance ensures the continuous and effective monitoring of patient safety. The field is rapidly evolving, and conferences like the annual SCRMP are exceptional platforms, providing an invaluable opportunity to better understand these transformations, bringing together diverse perspectives from across the industry. I am happy to join with this laudable initiative to inspire, collaborate, and learn, together with experts across all domains of drug safety.

Dr.Himanshu Bhatnagar
Medical Director, Parexel International

Message from Nikhil C Bhanumati

The world of drug safety is evolving faster than ever. Today, it' not just about running clinical trials—t' about understanding how medicines perform in real life, with real people. This shift creates exciting new roles for researchers, pharmacists, and healthcare professionals.

For students and young professionals, this is a great time to step in. Whether you'e interested in science, data, or patient care, there' a place for you in this field. Keep learning, stay curious, and remember—our work has the power to save lives. My best wishes to everyone attending and organizing this important event.

Nikhil C Bhanumati
Global Principal Clinical Lead,
Thermo Fisher Scientific

Message from Dr. Umama Yezdani

This initiative embodies our vision to unite diverse voices in science and medicine, driving impactful change for global health. My heartfelt thanks to all who have worked tirelessly to make this possible.

Dr. Umama Yezdani
Senior Regulatory Associate,
Freyr Solutions

Message from Dr. Harsimran Kaur

As we gather to discuss the latest advancements in clinical research and healthcare, I'm reminded of the critical importance of Pharmacovigilance in ensuring patient safety. The proactive identification, assessment, and mitigation of risks associated with medicinal products are essential to protecting public health. I eagerly anticipate delving into the latest cutting-edge strategies and innovative approaches that are revolutionizing the field of Pharmacovigilance, and sharing insights on how we can collectively elevate patient safety to new heights.

Dr. Harsimran Kaur
Senior Manager,
Medical Safety

Message from Nishith Vyas

The future of clinical research has immense potential. One of the very integral parts of the overall drug development within a pharmaceutical company. There are many areas to explore like Biostatistics, Clinical Data Management, Clinical Development, Clinical Operations, Medical Affairs and Health Economics and Outcomes Research that one can deepen his or her understanding and choose a career option. Come join us at SCRMP International Annual Conference where we will discuss various prospects of Clinical Research.

Nishith Vyas
Global Management Consultant,
Novartis

Message from Dr. Rohini Pandey

As the clinical research landscape transforms, our role in Pharmacovigilance is more critical than ever. We're not just monitoring safety—e'e shaping it. With AI, real-world data, and global collaboration at our fingertips, we must lead with agility, think proactively, and embed patient-centricity into every decision. Pharmacovigilance must evolve from reactive safety monitoring to proactive risk intelligence. Let' simplify processes, amplify insights, and drive smarter, faster, and safer outcomes—together.

Dr. Rohini Pandey
Director PV Operations, ABOTT

Message from General Secretary

"It is my privilege, as Co-Founder and General Secretary of the Society of Clinical Research and Medical Professionals (SCRMP), to welcome you to our Annual International Conference and this special edition of our magazine. This platform reflects our commitment to advancing research, fostering collaboration, and inspiring innovation across disciplines. I thank every contributor, speaker, and participant for making this event a milestone in our shared journey."

Mohammad Gayoor Khan
Global General Secretary &
Co Founder of SCRMP &
EndricScience ©

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