REIMAGINING PATIENT SAFETY

Connecting data across the value chain allows timely access to critical information, enabling better decisions and protecting patients from avoidable harm.

Over the past 15 years, pharmacovigilance has grown beyond its traditional compliance role to become an active strategic partner in innovating operations, improving patient outcomes, and ensuring medical governance. Its scope and workload have also grown exponentially during this period, with an increasing number of data sources and adverse events.

Case processing now accounts for 40 to 85% of pharmacovigilance budgets, with case volumes growing at a rate of 15 to 20% per year.[1,2] At the same time, overseeing drug safety is even more challenging as global operating models increase in complexity and regulatory requirements continue to evolve.

(Source: Veeva Systems)

1 FIGURE 1: GROWING PHARMACOVIGILANCE CHALLENGES

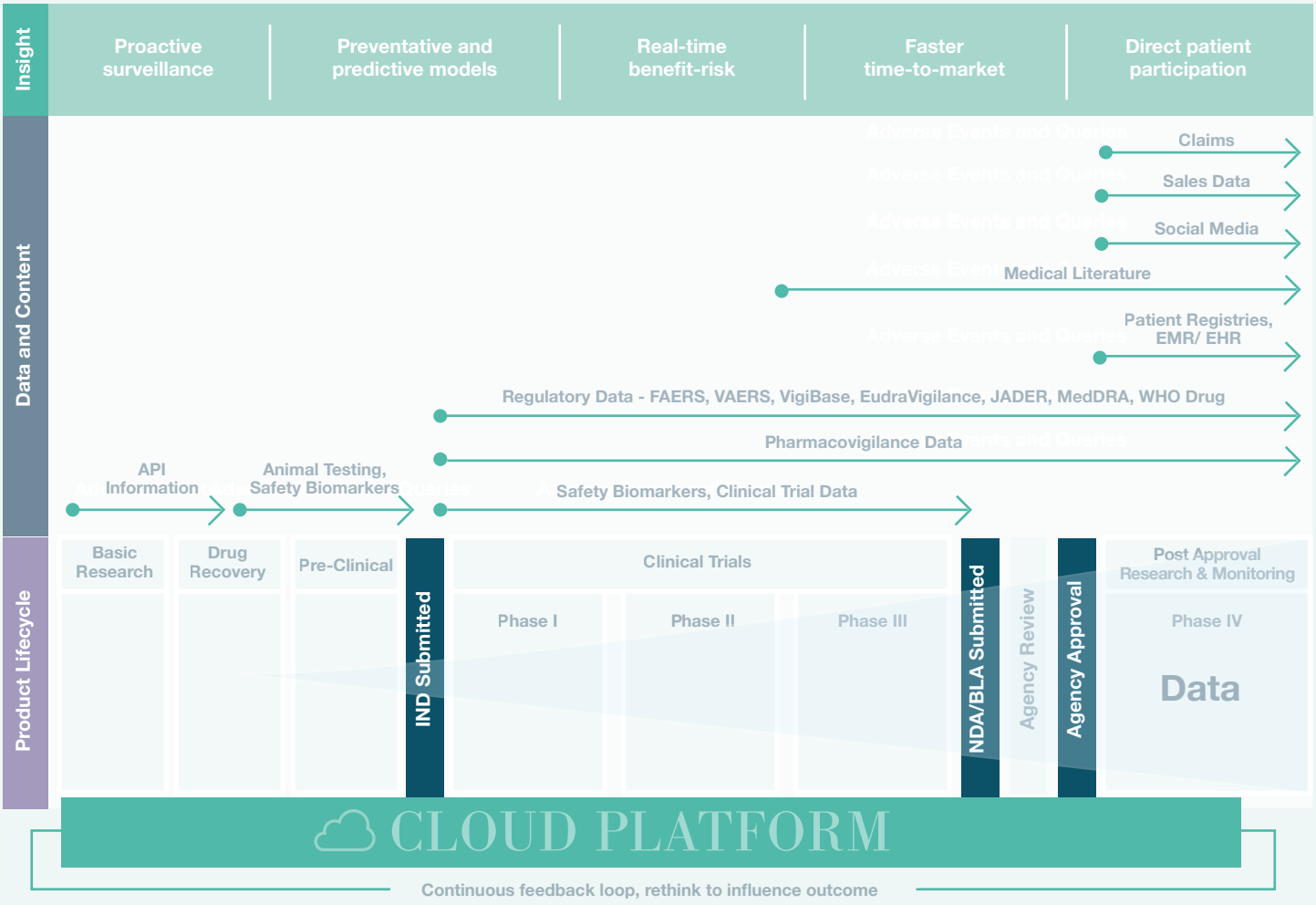
Preventable patient safety issues are still a leading cause of patient death worldwide, with societal costs between $1–2 trillion each year in the US and UK alone.[3] Initiatives such as The Global Patient Safety Action Plan 2021-2030,[4] adopted by the World Health Assembly, provide a much broader context for improving pharmacovigilance. The plan envisions "a world in which no one is harmed in health care, and every patient receives safe and respectful care, every time, everywhere." It sets drug safety goals within systemic efforts to address healthcare challenges and drive medical governance oversight while prioritising patient safety, data integrity, and R&D innovation.

Technology is critical to achieving these goals and the industry is making progress, embracing new ways of thinking and unique safety approaches. More safety leaders are reimagining patient safety with modern systems that can move the industry toward a predictive, preventative, and participatory model for pharmacovigilance.[5]

Increasing drug safety role and visibility

Distributed data ownership limits opportunities for harnessing insights from safety data for cumulative benefit-risk analysis throughout the product lifecycle. Aided by technology and access to real-time data, analytics, and insights, medical safety teams can play a key role in minimising or mitigating risks and improving patient outcomes.

With change happening around data transparency, like the mandatory public sharing of market performance data and benefit-risk study results, safety teams must be on an equal footing with drug efficacy and effectiveness. Modern pharmacovigilance systems on a single cloud platform can improve regulatory compliance and provide a competitive advantage.



(Source: Veeva Systems)

2 FIGURE 2:

DATA ACCESSIBILITY ACROSS THE END-TO-END PRODUCT LIFECYCLE ENABLED BY A CLOUD PLATFORM

Reducing the operational and compliance burden
Safety functions have adopted decentralised models to better support local pharmacovigilance needs. Still, the scope of data required to remain compliant has increased with regulatory changes, including:

- EU pharmacovigilance (GVP)[6] and subsequent requirements globally by market, portfolio type, etc.
- Combination product and vaccine requirements
- Related GxP requirements such as Identification of Medicinal Product Dictionary (IDMP)[7]
- EU Medical Device Regulation (EU MDR)[8]
- EU Clinical Trials Regulation (EU CTR)[9]
- Real-world data[10] requirements for clinical trials

The complexity of global operating models and multi-stakeholder environments requires strong governance. Organisations with siloed drug safety systems or reliance on paper-based and manual processes don't have a holistic view of pharmacovigilance and will have a hard time keeping up.

Cloud-based technologies and other innovations centralise safety information and enable access and collaboration across internal and external parties. With global visibility, controlled processes, and harmonisation of data and content, teams can proactively manage pharmacovigilance and improve compliance.

For example, companies can leverage modern safety content management applications to reduce pharmacovigilance system master file (PSMF) overhead while quickly meeting regional requirements and gaining global visibility. This is significant progress for the industry since over 60 markets globally require a PSMF, or an equivalent document. Providing a core PSMF binder of all content that local markets can reference, with local annexes or appendices, and empowering teams to keep information up to date reduces the Qualified Person for Pharmacovigilance (QPPV) burden and strengthens compliance.

Modern safety applications also deliver flexibility to integrate data from other systems (e.g., regulatory, quality, and clinical) more easily. This ensures data integrity, traceability, and real-time access to information across the pharmacovigilance ecosystem.

Improving patient outcomes and driving innovation
Safety science is becoming more complex because of growing regulatory scrutiny, increased customer demands, and a safety data explosion. COVID-19 has heightened the focus on safety and public health benefit-risk discussions, and local regulators in emerging markets have responded with more stringent regulations.

Innovative approaches such as real-time data exchange, coordinated inspections, and global collaboration between different regulatory agencies are becoming routine. The pandemic has made it more important than ever for marketing authorisation holders (MAH) to be agile and act quickly on safety concerns because it only takes a few hours or days for local market issues to become global incidents.

The demand for greater transparency and comparative benefit-risk analysis throughout the product lifecycle has shifted questions of ownership and accountability beyond the QPPV and head of safety to the C-level. Chief medical officers and safety officers are becoming accountable for the end-to-end process and timely and transparent communication of drug benefits versus risks to patients, healthcare providers, and related stakeholders.

> "COVID-19 has heightened the focus on safety and public health benefit-risk discussions"

Emerging regulations will move safety beyond the control of PV
As patients and healthcare providers assume a more active decision-making role and new models for data governance emerge, strategic transformation promises to affect every aspect of healthcare, from increased patient access to questions of treatment decisions, safety, and transparent public communications.[11,12] Health data is the new currency that will drive innovative solutions for safety issues, public health challenges, and preventive health measures.

More product benefit-risk and safety data will not be controlled just by pharmacovigilance as emerging regulations shift ownership of health information under federated governance models.[13] At the same time, external data sets that are new to drug safety teams, such as social media and sales data, will become more critical to pharmacovigilance.

Several European initiatives will have significant implications for drug safety data and, in general, healthcare data:

- EU Health Data Space will allow secure exchange of data, such as electronic health records and genomics and disease registries, while ensuring privacy[14]

- EU Data Governance Act sets out rules for data reuse and data sharing with data intermediaries acting as data sharing service providers.[15] Companies, notably Roche, are embracing data altruism and data availability using a common framework[16]

- EMA EU Telematics strategy paves the way for EU regulatory master data, governance, interoperability, digitisation, and regulatory innovation to increase quality, speed, and collaboration[17]
- EUDAMED database follows the EudraVigilance model, providing data transparency, patient engagement, and real-time on-market device performance communications
- EU electronic product information (ePI) initiative aims to bring together data availability and governance efforts with better communication of drug risks and benefits through more effective labels and product information sheets targeted to end-users through digital channels.[18]

The existing disconnect between pharmacovigilance and other departments like marketing or commercial systems makes it challenging to manage the increased burden of business-driven programmes such as patient support, market research, and product registries.[19]

"Health data is the new currency that will drive innovative solutions for safety issues"

Moving toward greater data transparency and predictive PV

Although the collection and reporting of key pharmacovigilance risk indicators to enterprise risk committees are common practice, identifying the correct leading indicators earlier in the R&D stage is becoming crucial to protect patient safety. Supported by innovative technologies, safety teams can quickly analyse large data sets as well as find and share insights to reduce risk.

As use of modern technologies grows, companies need to address key questions, such as:

- How can we design an integrated pharmacovigilance system that can monitor performance and help with early interventions?
- What are the impacts of federated data governance and a growing number of benefit-risk data residing outside the organisation?
- How are we managing emerging risks as we leverage AI and predictive algorithms from R&D through commercialisation and post-market surveillance?

More companies are leveraging artificial intelligence (AI), analytics, and predictive models instead of traditional approaches via retrospective audits and Corrective Action and Preventive Action (CAPA) plans.[20]

"Trust will be the central currency"

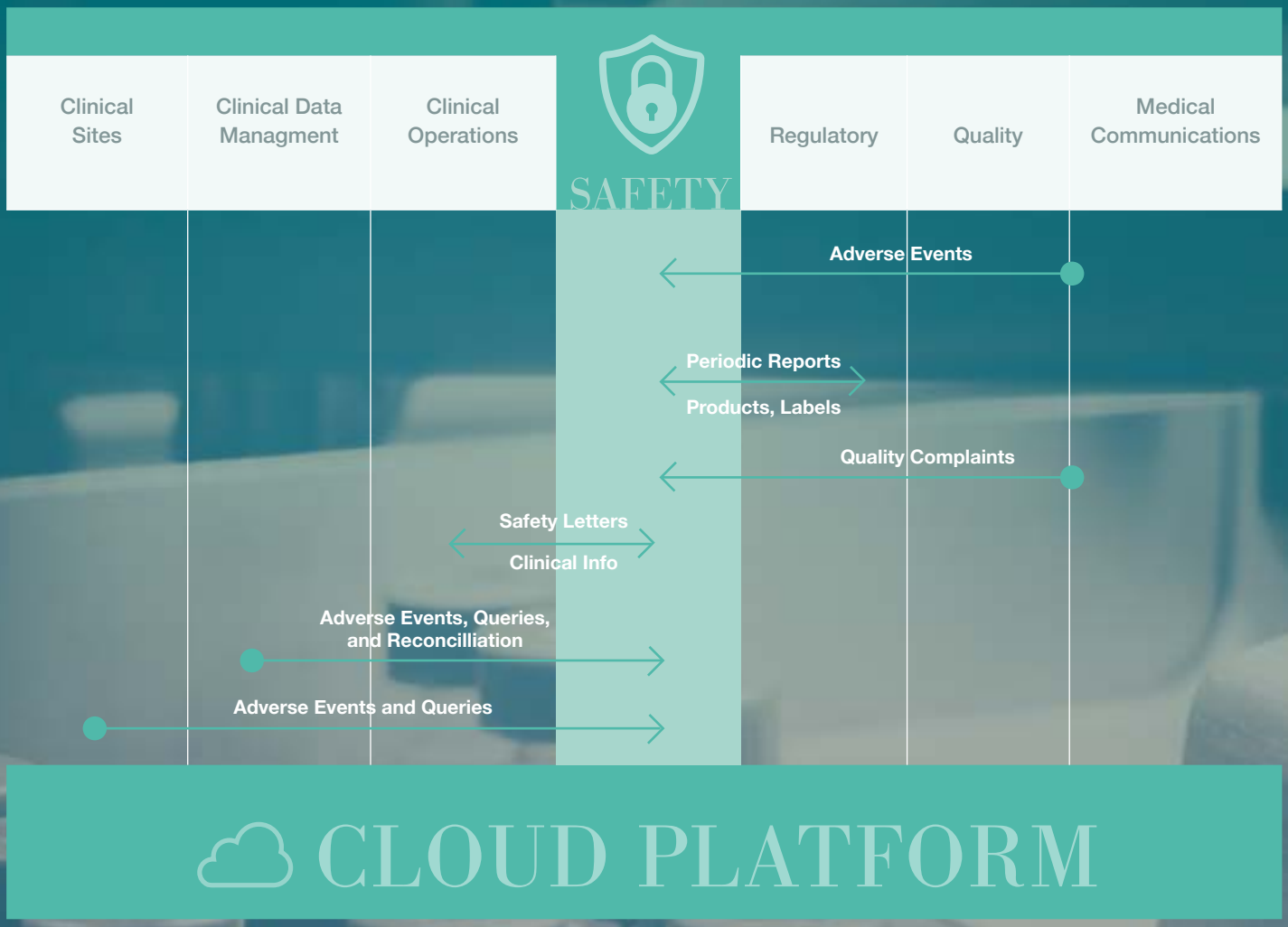
Trust will be the central currency for building a unified benefit-risk data platform

The development of more agile and interactive drugs and medical devices will require product data to be accessible cross-functionally to influence better outcomes. Progress in this area has been slowed by a lack of visibility across systems that prevent the right data from reaching the right people at the right time to act.

Having end-to-end drug safety data on a single platform delivers data accessibility, a prerequisite for meeting new safety communication transparency requirements, and establishing trust.[21,22] It also permits rapid response and proactive communication during crises.

3

FIGURE 3: FUTURE INTEGRATED SAFETY VISION



(Source: Veeva Systems)

In the digital age, companies have far less control over their product message than they did in the past.[23] The need for readiness and speed became abundantly clear during the pandemic. Companies had to manage business continuity virtually while preventing patients and the public from receiving misinformation before they receive the facts about a drug or product.[24]

Under the current climate, speed and data integrity have become even more critical for pharmacovigilance teams. Key questions to ask are: How are patients being protected? Is the scientific integrity of the data sufficiently robust?

A single platform that connects data and content across the end-to-end value chain from patients to product development improves data quality and communication and provides a more holistic view of safety. By taking a platform approach, the industry can enable a data-centred approach to help transform healthcare for the better.

Supporting good data practices with a connected platform lays the foundation for data sharing, aggregation, analytics, and insights. It also provides visibility into a complete audit trail, improves data control, and strengthens security.

The efficiencies and broader impact of using one technology platform can help solve key safety issues, such as:

- Signal to label: this has been a consistent inspection finding for the past ten years. The ability to connect signal workflow metrics with regulatory, technical operations, labelling, and supply chain is critical.
- Better connections with marketing and commercial: being able to manage patient and healthcare professional (HCP) queries and product complaints can enhance treatment adherence and prevent medication errors. Closer collaboration between commercial and safety can reduce the governance risks associated with solicited programmes like market research, patient support programmes, registries, and organised data-collection systems. It also makes it easier to meet the need for effective measures and outcomes information, which are making patient experience data and outcome metrics increasingly important in regulatory decision-making.
- Manufacturing, supply, and distribution quality concerns: using technology on a single platform that delivers better connections across quality and safety systems allows quality challenges to be addressed in real-time. This can also deliver local, regional, and global visibility and oversight for rapid response and crisis management.
- Clinical trial safety, effective medical monitoring strategies, and integrated development safety plans: all of these require real-time data flow for rapid action.
- Access to cumulative lifecycle benefit-risk data: this can drive integrated development and post-market decisions, including real-world patient experiences. A platform that allows for end-to-end processes delivers real-time insights to influence behaviour change and enable proactive actions that can optimise patient safety and health outcomes.

Healthcare transformation and the speed of change, accelerated by the pandemic, have forced the industry to rethink how its stakeholders interact across the ecosystem. Technology is proving critical in helping to protect patients, public health, and scientific data integrity.

Today, pharmacovigilance organisations are focusing more on what they need from technology to minimise daily disruption and increase efficiency. With a unified and connected platform, safety teams can sense and act proactively to drive innovation and early access to therapies. In the end, this can enhance societal value, and that is what safety is all about.

"With a unified and connected platform, safety teams can sense and act proactively"

REFERENCES

[1] "The Evolving Pharmacovigilance Landscape," Deloitte US/ Lifesciences and Healthcare White Paper, 2018, https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-transforming-pharmacovigilance.pdf

[2] M. Raizada, "Digitally Transformed Pharmacovigilance," a Navitas Life Sciences White Paper, 2018.
"Pharmacovigilance 2030". Peter Arlett, Sabine Strauss and Guadi Rasi, Clinical Pharmacology & Therapeutics, 2020

[3] World Health Organization, The Global Patient Safety Action Plan 2021-2030 , WHO Technical Document, 3 August, 2020, https://www.who.int/publications/i/item/9789240032705

[4] Big win for patients: Global Patient Safety Action Plan 2021–2030 adopted by 74th World Health Assembly www.iapo.org.uk/news/2021/jun/8/big-win-patients-global-patient-safety-action-plan-2021%E2%80%932030-adopted-74th-world#

[5] P. Arlett, S. Strauss, and G. Rasi, "Pharmacovigilance 2030,"Clinical Pharmacology & Therapeutics, 2020

[6] EMA, "EU Good Pharmacovigilance Practices," www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices

[7] EMA, EU Data on Medicines: Identification of Medicinal Product Dictionary (IDMP)
www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview

[8] EC, EU Medical Devices Regulation
https://ec.europa.eu/health/md_sector/overview_en

[9] EU Clinical Trials Regulation https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation

[10] FDA Real World Evidence Approval Decision Making Drug Effectiveness https://www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness'

[11] EMA, "EMA Regulatory Science Strategy to 2025," www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy#regulatory-science-strategy-to-2025-section

[12] Cumberledge Report https://www.immdsreview.org.uk/index.html

[13] Patient and Public Involvement Strategy 2020-2025 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022370/Patient_involvement_strategy.pdf

[14] EC, EU Health Data https://ec.europa.eu/health/ehealth/dataspace_en

[15] "Proposal for an EU Data Governance Act," iapp.org, iapp.org/news/a/proposal-for-an-eu-data-governance-act-a-first-analysis/
[16] Roche, "Roche Policy on the EU Health Data Space," www.roche.com/sustainability/policy-eu-data-health-space.htm

[17] EMA, "EU Extended Telematics Strategy Implementation and Roadmap,"www.ema.europa.eu/en/documents/other/extended-telematics-strategy-implementation-roadmap-2019-2020_en.pdf

[18] P. Chaudhary and V. Shetty, "E-Labeling: Change is Underway," Pharmaceutical Executive, June 29, 2020, /www.pharmexec.com/view/e-labeling-change-underway

[19] EMA, "Guidelines for Registry-Based Studies," www.ema.europa.eu/en/guideline-registry-based-studies-0

[20] EMA, "Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation," 19 & 20 April, 2021

[21] FDA, "Patient-Focused Drug Development Approval Process," www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

[22] "Edelman Trust Barometer 2021," Healthcare Sector: Global, Edelman UK, www.edelman.com/sites/g/files/aatuss191/files/2021-05/Global%20Health%20Sector%20Barometer.pdf

[23] "Into the Infodemic," Uppsala Reports, 2021, www.uppsalareports.org/articles/into-the-infodemic-countering-covid-s-medicine-myths/

[24] C. Paul, "Health Trust in a COVID-19 World: A Unique Opportunity for Pharma," Edelman UK, June 19, 2020, www.edelman.co.uk/research/health-trust-covid-19-world-unique-opportunity-pharma

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