

The Impact of Technology on Pharmacovigilance Over 25 Years and Beyond

Evolving technologies and pharmaceutical standards have significantly enhanced medicinal product safety in the last few decades, with innovations in data science promising even greater future achievements. Discover key milestones that have improved safety and learn how Oracle continues to lead the way to next-generation multivigilance.

1990 - 1999

The (final) paper decade

During most of this decade, like in previous decades, adverse events are documented on paper forms and shared by postal mail or fax, and signals are often tracked via binders or spreadsheets. IT departments build and maintain homegrown safety systems separately.

Industry milestones

- 1990**
FDA VAERS program is established
CIOMS-I Report includes standard AE paper form
- 1992**
CIOMS-II Report includes standard AE line listing
- 1993**
FDA MedWatch program is established
- 1995**
EMA is established
- 1996**
ICH publishes PSUR Step 4, standardizing aggregate AE analysis

1997 Birth of Argus and Empirica

Commercial-off-the-shelf (COTS) safety solutions



Safety case management
Includes the CIOMS-I, CIOMS-II, MedWatch, and PSUR reports



Safety signal management
Includes the GPS algorithm invented by Dr. Bill DuMouchel in collaboration with FDA



2000 - 2009

The electronic decade

The industry sees an accelerated shift from homegrown safety systems to COTS solutions such as Argus and Empirica, enabling electronic reporting, more accurate signal detection, and standardization.

268%

increase in the number of AE reports in FDA FAERS from 1990 to 2000

Industry milestones

- 2001**
ICH publishes E2B(R2) Step 4, defining the first electronic AE report
- 2003**
MHRA is established
- 2004**
PMDA is established
- 2005**
By 2005, Argus becomes the market leader for case management, and Empirica becomes the market leader for signal management

Oracle makes strategic acquisitions

- 2002**
NetForce is acquired for its pharmacovigilance capabilities
- 2004**
SiteWorks is acquired for its clinical R&D capabilities
- 2009**
Relsys is acquired for its pharmacovigilance capabilities

Major releases

- ARGUS**
 - Releases as a web application
 - Adds the E2B(R2) report and other major enhancements
 - Affiliate and Argus Japan modules are introduced
- Empirica**
 - Expands customer base from the FDA to include biopharmas
 - Adds MGPS and ELR algorithms and other major enhancements
 - Topics module is introduced for signal management

2010 - 2019

The cloud decade

Traditional on-premise safety systems start moving to the cloud, further supporting the expanded scope of electronic and periodic reporting. Multitenancy, integrated analytics, and better signal detection algorithms are introduced, promoting greater insight and accuracy.

Industry milestones

- 2010**
ICH publishes DSUR Step 4
- 2012**
GVP Module IX comes into effect
- 2012**
ICH publishes PBRER Step 4

Oracle adopts industry standards

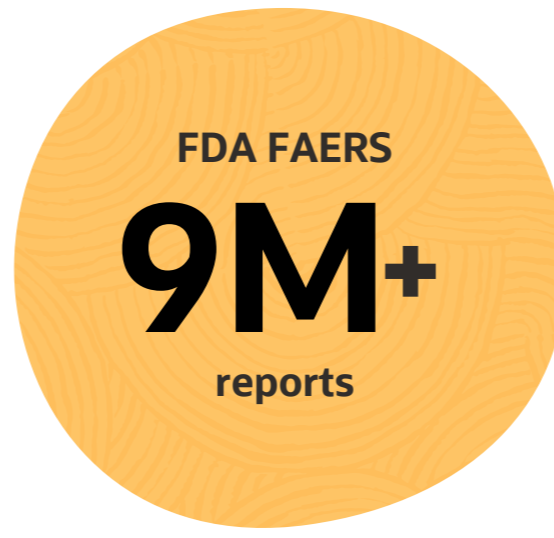
- 2011**
Oracle adds the DSUR to the Argus report library
- 2012**
Oracle creates a GVP Module IX workflow configuration in Empirica
- 2013**
Oracle adds the PBRER to the Argus report library

2011

- Argus Cloud
- Argus Analytics
- Argus Multitenancy

2012 — Oracle Empirica's RGPS algorithm is invented by Dr. Bill DuMouchel and Dr. Rave Harpaz, combining the advantages of the MGPS and ELR algorithms into one hybrid method

2014



Regulatory reporting milestones

- ICH publishes E2B(R3) Step 4
- FDA goes live with eMDR and eVAERS
- EMA goes live with E2B(R3)
- PMDA goes live with E2B(R3) and J-DSUR

Oracle makes strategic acquisitions

- Phase Forward is acquired for its pharmacovigilance and clinical R&D capabilities
- ClearTrial is acquired for its clinical R&D capabilities
- goBalto is acquired for its clinical R&D capabilities

Major releases of Argus and Empirica

- Argus incorporates ICH E2B(R3), eVAERS, eMDR, and J-DSUR reports
- Argus integrates with the Oracle B2B for EDI gateway
- Argus supports EMA E2B(R3), PMDA E2B(R3), and IDMP
- Empirica adds RGPS, IC, case scoring, and increased frequency algorithms

2019 Empirica introduces a new user interface with embedded visualizations



2020 - 2029

The data science decade

The industry is facing exponential growth in case volumes and more data sources for signal detection. The focus is now on finding ways to use data science with its toolbox of leading-edge technologies to eliminate manual workflows, gain safety insights, and keep up with changing regulations.



- 2020**
Oracle creates the **v-safe** post-vaccination health checker app for the US CDC to help in the fight against COVID-19
- Argus** adds the MFDS E2B(R3), NMPA E2B(R3), and MIR reports to its library
- Empirica** introduces a redesigned user experience for topic management

Birth of Safety One Intake: The first AI-powered Oracle Life Sciences application, designed to make safety case processing faster with better quality and compliance:

- Automatically extracts AE data from any safety source document
- Reduces manual data entry, allowing staff to focus on high-value activities
- Improves efficiency, accuracy, and consistency of case processing

2022 ORACLE Cerner

Oracle acquires Cerner, a major supplier of health information systems, adding a new tool to the Safety One data science toolbox: real-world data

Paving the way to improved safety

Using an innovative mix of cutting-edge technologies and industry expertise, Oracle's safety data science team will continue to find ways of applying the right solutions to solve specific challenges, deliver value, and evolve the Safety One Platform.

Safety One Platform

Innovative evolution via data science



Next-generation solutions for pharmacovigilance and multivigilance

Discover how Oracle is improving safety by driving greater insight, efficiency, and compliance in case management and signal management.

oracle.com/safety >

