

VIDEO TRANSCRIPT

INTIENT™

PHARMACOVIGILANCE

The INTIENT platform enables insights and collaboration across life sciences and healthcare.

INTIENT's core capabilities include:

- a compliant and secure infrastructure,
- machine learning-ready data management tools,
- DevOps and testing tools, and
- common runtime.

INTIENT also includes specific capabilities across four product suites:

- Research
- Clinical
- Pharmacovigilance and
- Patient

The platform is powered by Google Cloud and supported by the INTIENT network partner ecosystem, giving access to independent software, services, hardware and content providers on Google Cloud's open architecture.

Google Cloud's innovative technology also enables secure, compliant application of AI and advanced analytics.

Let's have a closer look at INTIENT PV:

INTIENT Pharmacovigilance helps life sciences companies collect, manage and learn from a wide spectrum of patient safety data.

It provides earlier insights, better data transparency and reporting, and more timely discovery of potential adverse events.

Michael, a Safety Monitor, has logged on to the "Insights Tool", one of the INTIENT capabilities:

He's using FAERS, the FDA Adverse Event Reporting System as the data source to conduct a periodic review.

In this case, he selects "Aspirin" as the drug he will focus on for this review session.

He begins with the "Retrospective Analysis" and gets a dashboard of charts and graphs for 2019.

He identifies a significant amount of records available for patients over 60 with serious outcomes.

In a majority of cases, he sees there is also use of a concomitant drug.

Michael explores if there is a trend and finds that for Aspirin, there has been no significant change in the number of cases reported, but an increase in serious outcomes.

With the Disproportionality Scores, Michael focuses on a few significant events.

He selects GPS, or Gamma-Poisson Shrinker, as his statistical method, that has a pre-defined threshold of equal or greater than two:

A high score of association can be seen in the larger squares.

To verify his findings, he selects another method for comparison and captures this information as a "comment" at the bottom of the page.

Looking at the individual case reports, Michael discovers a pattern for patients with Chronic Kidney Disease or Acute Renal Failure:

The dose form and quantity for these events appear to be similar in all cases.

The primary case ID allows for further evaluation if required.

To compare data over time, Michael checks the Periodic Comparison overview.

Since a signal change from No to Yes shows a need for further investigation, Michael selects all No-to-Yes combinations for Aspirin.

Both Chronic Kidney Disease and Acute Kidney Failure have moved over a threshold of 2 set for "GPS" and can now be identified as Potential Signals.

Michael can see the variation between the scores for the statistical methods in the Statistical Comparison; Color coding shows positive and negative changes.

Throughout his analysis, Michael documents his observations in the system by adding comments at the bottom of the pages.

Those comments are documented here, along with his name and date, to complete the audit trail for regulatory compliance.

Finally, as per the findings of the analysis of data and post evaluation, the Benefit-Risk Profile of the drug can be updated.

This demonstrates only a small portion of the value that INTIENT Pharmacovigilance delivers to its clients each and every day.

This product suite offers:

- Integrated Pharmacovigilance Data & Operations Enablement
- Pharmacovigilance Insights as a Service

And INTIENT PV is an integral product suite within the INTIENT platform, a comprehensive, unique platform that enables insights and collaboration across life sciences and healthcare.

Please visit our website at [Accenture.com/INTIENTPV](https://www.accenture.com/INTIENTPV) to learn more.