



Bionical Emas Introduces Veeva Vault Safety

By utilising our highly experienced UK based team, combined with Veeva Vault Safety, the Bionical Emas Pharmacovigilance Team deliver a regulatory compliant and cost-effective solution, to outsourced drug safety activities.

Ensuring the benefit risk balance of a pharmaceutical product is imperative. The global trend is an intensification of Adverse Drug Reaction (ADR) reporting, with the aim to target spontaneous reporting, to better estimate the incidences of 'known' ADRs. Accompanying this is a push towards automation and Artificial Intelligence (AI) to improve accuracy, quality and consistency around adverse event data¹. Bionical Emas is continuously developing and implementing processes and systems, to support clients in meeting these trends. Transitioning to Veeva Vault Safety, is part of Bionical Emas' strategy to ensure we are able to continually support our clients in an ever-changing environment.

The Bionical Emas Pharmacovigilance Team are strongly positioned to capture and process safety data from a range of sources, such as Early Access and Clinical Development Programs to ensure our clients safety requirements are managed and remain compliant to Good Pharmacovigilance Practice.

In April 2021, Bionical Emas will become the first CRO in the UK to utilise Veeva Vault Safety. The combination of Bionical Emas' ability to manage and process Post-Marketing, Clinical Trial and Expanded Access data, via Veeva Vault Safety's powerful and flexible solution, will enable our clients to maximise their product safety data.

Veeva Vault Safety is a leading drug safety solution for the collection, management, and real-time oversight of adverse events, delivering informed decisions and improved compliance. Veeva Vault Safety improves PVG oversight by providing real-time reports and dashboards, while also providing active monitoring with automated notification of issue detection for Adverse Events of Special Interest (AESI), Designated Medical Event (DME's), Important Medical Events (IME's), and Watchlists. The Veeva Vault Safety system can automate and track safety cases with standard and configurable workflows while providing assignment, routing, email notifications, escalation, and tracking of tasks for groups or individuals.

By using Veeva Vault Safety, Bionical Emas are enabling our clients to maximise the safety profile of their products in one centralised and consolidated location, managed by our in-house team of experts to provide end-to-end product lifecycle safety management. This single source and Veeva Vault Safety's ability to generate a range of data outputs mean Bionical Emas PVG can provide clients with usable data quickly and efficiently for use in risk management, aggregate reports and reconciliation activities, all of which Bionical Emas PVG offers as in-house capabilities.

The benefits of Veeva Safety Vault, are featured below:

- Provide Real-time reports and dashboards for both Bionical Emas and its clients, enabling visibility for risk mitigation and safety compliance
- Streamlines Safety Case Management and gain efficiencies with a safety solution built for today's regulations and best practices
- A single cloud platform for safety/pharmacovigilance, clinical, regulatory, and quality eliminates silos and drives end-to-end safety processes
- Near future solutions, designed to link other Veeva systems

Bionical Emas provide our clients with a pharmacovigilance service tailored to their needs. Bionical Emas provide clients with the reassurance that as their product(s) develop, our systems and processes also develop, to enable our clients to efficiently scale-up their pharmacovigilance activities whilst continuously maintaining high quality and compliant data².

References.

1. *The Future of Pharmacovigilance.*

<https://www.covance.com/content/dam/covance/assetLibrary/whitepapers/Future-of-Pharmacovigilance-WPCMA013.pdf>, 2019

2. *Real-time Management and Oversight of Events, Accessible at;*

<https://www.veeva.com/products/vault-safety/>