

CASE STUDY 

Implement a Reliable, Function Rich PV Solution that Delivers Lifetime Value at a Reduced Cost

Pure Drug Safety (PDS) acts as a drug safety services provider for pharmaceutical companies. Their day-to-day activities range from case intake and data management to regulatory submissions. To support their business, PDS required a dedicated, validated and cost effective Pharmacovigilance system. In particular it was critical that the solution would enable them to stay compliant with any regulatory changes that might arise.

Prior to the selection of the Ennov solution, PDS went through two bad experiences, the latter with one of the leading PV software vendors. According to the founder and managing director of PDS, over time, their previous solution became more and more expensive, with service not proportional to the "horrific costs" being incurred. There were many issues and ongoing problems which required more people to maintain and control the growing data volumes. PDS had no other option than to find a more reliable system—something they could offer as a dedicated and validated PV solution to their customers. It was essential that any replacement system was comprehensive, as PDS could not afford to offer any reduction in service or functionality to their clients. For PDS the right solution meant a good system with compliant functionality and the opportunity to work with expert people from a company wanting a long-term partnership with PDS. About Pure Drug Safety.



About Pure Drug Safety

PDS (Pure Drug Safety) is a Pharmacovigilance consultancy service provider based in the UK. Founded in 2005, PDS offers pharmacovigilance and regulatory services to healthcare and life science companies to help "Pharma make sense of drug safety". The PDS team has over 60 years of combined experience working alongside national and international and biotech companies. PDS have a range of clients not only in the UK, but also throughout Europe, the US, and the Far East.

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The Solution: Ennov PV

When facing the prospect of changing software, PDS thought it would be useful to evaluate the Ennov PV system, which had an excellent reputation within the PV community. PDS came to Ennov after dealing with a number of other system providers, annoyed that they were not being treated as a valued customer. PDS wanted a business partner who viewed them as more than just a revenue stream—they wanted someone that shared in the company's ethos and ambition. When evaluating the Ennov PV solutions, PDS was impressed with Ennov's expertise in the PV field their willingness to help PDS reach the next level in the company's evolution.

PDS became an Ennov customer in May and, remarkably, Ennov's PV was deployed into production by September. PDS was impressed by the speed and efficiency of deployment. As well, they had not expected the solution would be so easy to use as PDS were able to train the majority of their users using their own in-house resources.

From capturing adverse events, MedDRA coding, submitting single case reports to PBRERs, PSURs and DSURs, PDS now uses Ennov PV to support many pharmaceutical clients. By using Ennov PV, PDS are able to offer all of the pharmacovigilance services their clients require.



"We were happy to find the support and respect Ennov demonstrated, which we felt was quite rare in a shared business partnership."

Phil Turner,
Business Development Manager
Pure Drug Safety

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Within a year, Ennov PV gave PDS a comprehensive and time efficient solution that met all of their requirements for case processing, case reporting, MedDRA coding, signal detection and writing of PSURs.

Conclusion

- › **Time to Market:** PDS is a company that provides value to their clients through innovation. The Ennov PV solution simplifies PV data management, so PDS can focus more on the more complex aspects of their projects. This helps PDS exceed client expectations and helps the company realize their goal of organic and profitable growth.
- › **PV Expertise:** PDS realized that working with large software providers is not always the best for business. For them, a dependable partner with deep expertise was a better fit.
- › **Resource Efficiency:** PDS spent a great deal of time, money and resources managing their previous PV systems. The Ennov PV system allowed them to offer their clients the same level of functionality without an increase in case processing costs.
- › **Room for Growth:** As PDS looks to expand their service portfolio even further, the Ennov PV system will be able to scale with them to help grow their business.