TOOLS FOR ADVERSE REACTION ASSESSMENT

Introduction to TARA PV

TARA PV was designed by a team of pharmacovigilance professionals, physicians and regulatory specialists who saw the benefits in a user-driven approach to processing and storing drug, device and vaccine adverse events in a secure safety database.

WHY TARA PV?

– Cost effective
– Flexible, competitive pricing
– Full user training
– Responsive support team
– Software upgrades
– Support portal access
– Project management

ISO 9001
Certificate No. GB2005816

ISO / IEC 27001
Certificate No. ISM7799365

Contact our India Representative

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With flexibility at its core, TARA PV is suitable for all pharmacovigilance requirements – with multiple product packages to match your needs and budget.

TARA PV was designed from the outset by pharmacovigilance professionals, rather than software programmers. The design team was based in a British CRO specialising in pharmacovigilance and clinical safety monitoring with extensive experience of safety databases. The software design was undertaken by our development partners i-dash Limited, supported by the computing department of Anglia Ruskin University in Cambridge U.K. The current TARA PV system is marketed and supported world-wide by MedGenesis Limited, which is an ISO 90001 and 270001 registered company based in the UK.

TARA PV provides a fully functional system offering a layout that is consistently simple, intuitive and most importantly user friendly in an affordable pharmacovigilance solution. TARA PV's features have allowed dramatic improvements to the quality and speed of case processing. The personalised control panel allows easy case management, and an integrated warning system highlights cases flagged for expedited reporting. The configurable workflow with automated e-mail notification, allows cases to be assigned to individuals or groups to distribute workload evenly within an organization. Wherever possible we avoid duplicate data entry and key fields auto-populate as the user progresses through the case and unnecessary fields in a particular case will not appear, giving a simpler cleaner interface. Other novel features include PubMed (Medline) searches, allowing article details and author names to be captured, increasing input speed, and dramatically reducing the risk of typographical errors. In addition to the input fields for medicinal products TARA PV has inbuilt fields for medical devices/combination products and vaccines and can generate the appropriate forms for regulatory reporting, such as CIOMS, MedWatch, VAERS etc.

✔ Compliant

TARA PV is fully E2B(R3) compliant and can import and export data in this format. In addition we have developed custom import programmes which have allowed our clients to transfer legacy data from other software systems. This would be the preferred solution if you wished to import fields other than those contained within E2B. TARA PV can also import data from clinical data management programmes such as Medidata RAVE using an EDI gateway.

✔ Capable

TARA PV has multitenancy capability allowing users to access multiple databases from a single administration module, whilst still allowing the designated system administrator to control user access to individual databases. We also offer as standard, two factor authentication for increased database security.

Compatible

TARA PV allows the use of the MedDRA and WHODrug dictionaries (subject to the appropriate licence) with automatic MedDRA coding for the event term and indications for medication. MedDRA updates are simple to apply and can be done by the system administrator: impact analysis and re-coding can also be performed following version change. Electronic reporting can be supported either through a portal or via a gateway to regulatory authorities and standard listings can be generated easily from within the application. TARA PV also has an integrated Power BI module included in the basic package, providing a powerful data analysis and signal detection tool that, in addition, can generate custom reports for many client requirements.

Certified

The TARA PV system and the associated safety databases are housed in the UK in tier 4 ISO 27001 data centres with multiple redundancy features. The back-up Schedule includes transaction logs every 30 mins, at least weekly full back-ups and daily incremental back-ups. All backups are off-site from the primary hosting location. In the event of data loss, the Data Centre supplier provides recovery services to restore the most recent back-up.

Thus TARA PV offers healthcare companies a powerful, fully functional package to support all the company's pharmacovigilance, reporting and signal detection needs in a user friendly, configurable and affordable software package.

We offer a series of pricing models, and also offers reductions in costs for not-for-profit and academic institutions including regulatory and other government authorities.

We are happy to discuss your requirements in detail, and to demonstrate the TARA PV system to you and your colleagues. We could then provide a tailored cost estimation for you upon request.

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