

COMPLIANT CASE PROCESSING & REPORTING IN THE EU USING ARGUS

Changing PV climate

Within drug development, the focus on risk management has significantly increased, as well as the complexity and size of clinical trials. Together with a relatively diminishing R&D budget, it has become a challenge to match regulatory requirements of an effective pharmacovigilance system, needed to protect patients from possible risk.



Activities

- Single global safety database
- Data migration
- Case processing
- Case reconciliation / sharing – partners
- E2B and ICH compliant
- Support data extraction for periodic reporting
- Advanced querying and reporting
- Visibility of KPIs and case processing metrics
- Datasource and support for signal detection on Argus AEs

Case Number	Age	Sex	Ethnicity	Country	Event	Medical History	Diagnosis	Outcome	Disposition	Date of Onset	Reported on	Reported by	Reported on
AZ_C1_COMP_PROD	21	Male	Hispanic/Latino	UNITED STATES	False	Cure All	0	0	Discharge	01-JUN-2002	01-JUN-2002	Pyrestra	01-JUN-2002
AZ_C1_COMP_PROD	12	Male	Hispanic/Latino	UNITED STATES	False	Cure All	0	0	Discharge	01-JUN-2002	01-JUN-2002	Pyrestra	01-JUN-2002
AZ_C1_COMP_PROD	17	Female	Hispanic/Latino	UNITED STATES	False	Immunize 30 m	0	0	Injection	01-JUN-2002	01-JUN-2002	Pyrestra	01-JUN-2002
AZ_C1_COMP_PROD	23	Male	Hispanic/Latino	UNITED STATES	False	Cure All	0	0	Discharge	01-JUN-2002	01-JUN-2002	Pyrestra	01-JUN-2002
AZ_C1_COMP_PROD	19	Male	Hispanic/Latino	UNITED STATES	Compensated	Diabetes	0	0	Injection	01-JUN-2004	01-JUN-2004	Pyrestra	01-JUN-2004
COMMON	17	Male	Hispanic/Latino	UNITED STATES	Unknown	Diabetes	0	0	Injection	01-FEB-2011	01-FEB-2011	Pyrestra	01-FEB-2011
ENTS_PRODUCT 1 CASE	18	Male	Hispanic/Latino	UNITED STATES	0	Test Drug 1	0	0	Injection	01-FEB-2011	01-FEB-2011	Pyrestra	01-FEB-2011
ENTS_1-LEADING ZERO	Years	Male	Hispanic/Latino	UNITED STATES	0	Test Drug 1	0	0	Injection	01-FEB-2011	01-FEB-2011	Pyrestra	01-FEB-2011
ENTS_1-003	23	Male	Hispanic/Latino	UNITED STATES	Death not due to AE	Wander Drug	0	0	Injection	01-JUL-2009	01-JUL-2009	Pyrestra	01-JUL-2009
ENTS_1-004	23	Male	Hispanic/Latino	UNITED STATES	Death not due to AE	Wander Drug	0	0	Injection	01-JUL-2009	01-JUL-2009	Pyrestra	01-JUL-2009
ENTS_1-005	1	Male	Hispanic/Latino	UNITED STATES	Death not due to AE	Wander Drug	0	0	Injection	01-JUL-2009	01-JUL-2009	Pyrestra	01-JUL-2009
ENTS_1-006	1	Male	Hispanic/Latino	UNITED STATES	Death not due to AE	Wander Drug	0	0	Injection	01-JUL-2009	01-JUL-2009	Pyrestra	01-JUL-2009



YOUR PV GATEWAY TO EUROPE

ARGUS

Oracle Argus can be regarded as the 'golden standard' pharmacovigilance safety database. By applying a multi-tenant approach and by using the Argus workflow manager we have lean processes and are able to offer this software as a cost-effective solution.

Implementation

Configuration, Validation and Migration often prove themselves to be challenging due to a very specific need for expertise. Thus, our services include planning and execution from your current database to the Argus MT Safety database.

Xendo team

Our dedicated case processing team is integrated with our, Medical Safety Science, Auditing, QPPV and Regulatory Affairs, combining over 25 years of experience. Together with Xendo's staff, who are experienced with the various agencies (including Japan), we can ensure global compliance in an ever-changing regulatory landscape.

Flexibility

As the system is very adaptive, all process steps can be managed by Xendo but clients can also choose to perform any of the steps internally (e.g. medical review, QC). Another possibility is that the client grants access to its own database, allowing our staff to process data on their behalf.

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