

technology

signal detection

integrity

database

collection



Safety*Drugs*

PHARMACOVIGILANCE SOLUTIONS

transmission

business intelligence

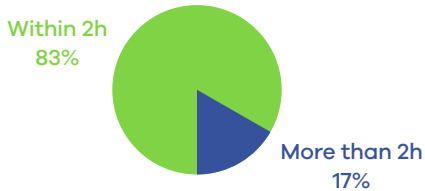
software

customization

report

About us

Ticket solving time

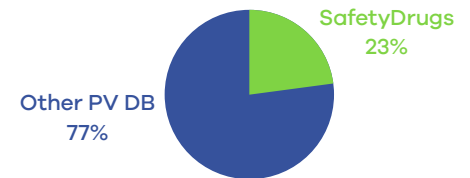


Max Application is an Italian company that develops Oracle database-based information systems and design customizable software, with a unique aim: optimize and simplify customer business processes.

We are recognized for the ability to listen, to understand and to solve the issues posed by our interlocutors. It is an Italian style to do things, appreciated all over the world.

Our leading product, SafetyDrugs®, is the best value-for-money solution for drug safety database in pharmacovigilance, used by about one out four of Italian pharmaceutical companies, and widespread in the areas covered by the EMA (European Medicine Agency) regulation.

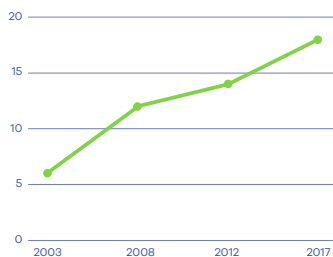
Italian market share



All solutions integrate with flexibility the IT structures, also thanks to a suite of products for Business Intelligence, area where we are proud of more than 10 years of experience.

Gamp5 (Good Automated Manufacturing Process) guidelines are used in the development process. For this reason our software assures to the customers the compliance with the requirements related to the different areas of application.

Staff increasment



The commitment of the work team has allowed, since 2007, to achieve the quality certification UNI EN ISO 9001 from the qualified Italian certification authority Italcert.

2003
Max Application foundation
Founding of Max Application Ltd. with offices in Biella and Turin (Piedmont, Italy).

2007
Pharma, the new business unit
Max Application decides to create a business unit dedicated to the pharmaceutical field.

2008
SafetyDrugs
It is released the first version of SafetyDrugs, the software specific for the pharmacovigilance management.

2007
Quality certification: ISO 9001
UNI EN ISO 9001 certification of the system Design, Development, Start-up, Maintenance and Support is acquired.

SafetyDrugs

SafetyDrugs is the pharmacovigilance solution that supports the capture, management, reporting and analysis of adverse events from clinical trials and from post marketing surveillance, including cases from literature, of any product category: drugs, devices, vaccines and cosmetics.

The software has been developed in compliance with the ICSR ICH R3 and EMA and FDA exceptions.

SafetyDrugs is customizable to user needs (workflow, controls, user profile, menus and screens).

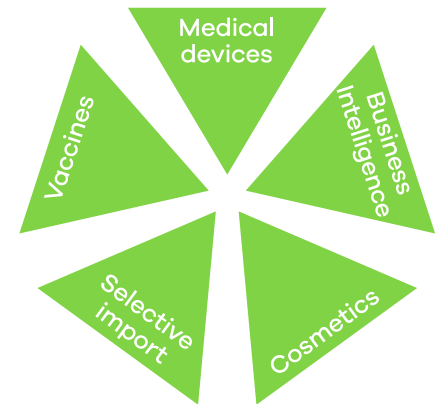
It is ready to use in few days thanks to the provided Validation Kit, which ensures a quick and inexpensive start-up.

Cloud modality

Our system is also available for rent in SaaS (Software as a Service) modality, which includes:

- constantly updated SafetyDrugs version
- high level data protection in a data centre Oracle with top security standards located in EU
- antivirus, service redundancy, connectivity, backup
- disaster recovery with stand-by database in a secondary datacentre located in EU
- compliance with European General Data Protection Rules.

Additional modules



Available in



2011

Business Intelligence

SafetyDrugs enriches itself by the business intelligence module which includes the Signal Detection analysis.

2013

Collaboration with Asgenia

A collaboration starts with Asgenia, the newly born services company of Assogenerici.



2016

SafetyDrugs 6

The development of new SafetyDrugs compliant with ICH E2B (R3) rules begins.



2016

Market share

The 23% of the Italian pharmaceutical companies manages pharmacovigilance with SafetyDrugs.

Main features

Functionalities

The software offers the following functionalities:

- Import and export of electronic reports both in XML and HL7 file format
- Selective Import, that allows the massive acquisition of HL7 files with relative preview mask prior to import for triage purposes
- SMART data entry mask, for a quick data entry of the case on a single mask
- Action Items, to help the management of any activity scheduled
- Transparent data encryption during both storage and transmission
- Interaction with Windows tools (Word, Excel, Acrobat, etc.)

Tools

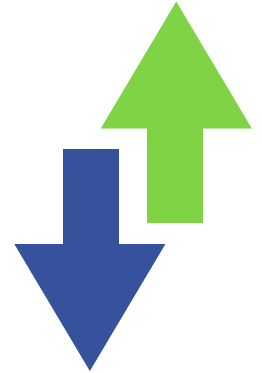
The system is fitted with the following tools:

- Gateway
- Report generator, to allow the customization of reports based on templates set by the user
- Message System, to send alerts, reminders and email with attachments, with customizable settings
- Backward and Forward Conversion tool (BFC)
- WHO and MedDRA dictionaries supporting
- Search for Duplicates, that allows to launch parametric search for duplicates

Reports

The database generates the following reports: CIOMS, Pregnancy form, PSUR, PBRER, DSUR, SMQ, MedWatch, MEDDEV, Quality check report, Cover report and other customizable listings for inspective purposes.

Data exchange



2017

Approaching newest technologies

First release of a Management and Business-to-Business solution, multi-language and fully web-based.



2018

Release of SafetyDrugs 6

Release of the new version of the pharmacovigilance software designed to comply with the ICH E2B (R3)

Business Intelligence

Max Application has designed and developed its own Business Intelligence software. Powered by Qlik®, it supplies flexible tools for queries and data analysis, through a set of dashboard. Every user can create his own query and data analysis models, according to his own needs, using simple and easy-to-understand tools.

The main characteristics of SafetyDrugs' Business Intelligence are:

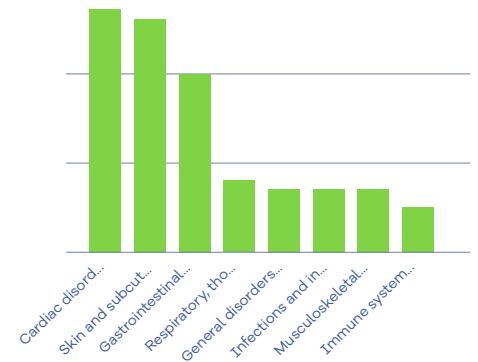
- adverse event data warehouse
- easy navigation and intuitive graphic
- drill-down analysis
- charts enabled to provide additional details
- customized data visualization using dashboards and graphic tools

With the Business Intelligence module it is possible to run Signal Detection analysis, that supplies:

- the evidence of drugs with disproportionally high statistical scores
- disproportionality statistical indicators (PRR, ROR, RR)
- Confidence Interval, CHI square and P-value tests
- the evidence of cases from Literature and the number of cases Unlisted, Unexpected, Fatal and Serious.

Additional analysis are available in the module:

- comparison among selected temporal interval
- quantitative analysis with possibility of qualitative analysis of detail on single case
- customized line listing
- KPI analysis, to monitor the cases management performances.





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