

Our solutions :

Pharmacovigilance - SafetyEasy PV™ :

- Already compliant with E2BR3 (HL7)
- E2B export and import
- E2B validation according to ICH E2B Business rules
- Integration of MedDRA dictionary
- Generation of PBRER, Signal Detection - PRR
- Bi-directional Gateway available for e-submission to Agencies (FDA, EV, ...)



Animal drugs - SafetyEasy VET™ :

- XML export and import
- Generation of regulatory reports
- Integration of VedDRA dictionary

Medical devices - SafetyEasy MD™:

- Generation of MedWatch, eMDR (HL7), MIR XML, FORM 5, FORM 6
- Vigilance across all three classes of Medical Devices

Cosmetic products - CosmEthics™ :

- The first and only solution fully dedicated to Cosmetovigilance
- Generation of SUE Forms, Security report
- Full management of skin tests

Nutraceuticals - SafetyEasy NUTRI™ :

- Compliance with international regulations

Secure

- Full Global Compliance
- Healthcare certified hosting
- ISO 27001 data Center
- Full continuity and backup

Easy

- Easy implementation & migration
- User friendly
- Easy adoption - eLearning
- Powerful data extraction and automation of tasks

Full Service

- Best in class support
- Quarterly Releases
- Full validation dossier
- Free maintenance

Flexible

- Full Web SaaS
- Configured easily and free of cost
- Unlimited number of users



AB-cube

More than software

Vigilance Software Solutions

Quick, easy and fully validated solutions for entry, import and electronic submission of adverse events

Animal Drugs



Cosmetics

Human Drugs



Medical Devices



Nutraceuticals



10

YEARS

700,000

CASES HANDLED

360

SOLUTIONS INSTALLED

1700

USERS

85

CUSTOMERS IN THE WORLD

AB Cube

Since 2006, AB Cube offers software solutions and services to the vigilance industry.

AB Cube's team consists of computer engineers who specialize in vigilance software development as well as pharmaceutical industry professionals. This structure helps AB Cube to meet all its users' expectations and needs.

Our Customers

AB Cube's customers include pioneer biotech companies, leading pharmaceuticals and cosmetics laboratories, academics, national agencies but also many vigilance service providers and CROs.

The diversity of our customers ensures our knowledge and experience in all areas of vigilance, whether spontaneous notifications or clinical studies.



We love CROs !

At AB Cube, we understand that vigilance service providers and CROs need flexibility and efficiency. We have designed a solution close to your needs.

AB Cube's software solutions help you save time and maximize your Return On Investment with:

- Centralized administration tools
- Large automation of tasks to help you save time and minimize mistakes
- Automatic generation of activity reports
- Gateways with National Agencies for easy submission of cases

For your business to remain highly flexible and adaptable, AB Cube guarantees:

- Speedy implementation of new databases, in 2 weeks maximum
- Unique implementation fee regardless of the number of databases you need
- High contractual flexibility

AB Cube's safety solutions are:
FDA 21CFR part 11 compliant
 &
Validated according to GAMP 5
 The full validation dossier is provided



Our Systems

AB Cube solutions allow to manage all vigilance processes from data entry to reporting:

- Management of spontaneous, literature and clinical study cases worldwide
- Audit trail / Case history for all actions performed on the system
- Edition of regulatory reports (Line listings, Summary Tabulations, CIOMS, MedWatch, E2B XML...)
- Query module with Excel file generation, link to SAS or Business Object
- Integration of MedDRA coding with SMQ
- Access to National Agencies' drugs databases
- Fully customizable workflow
- ...