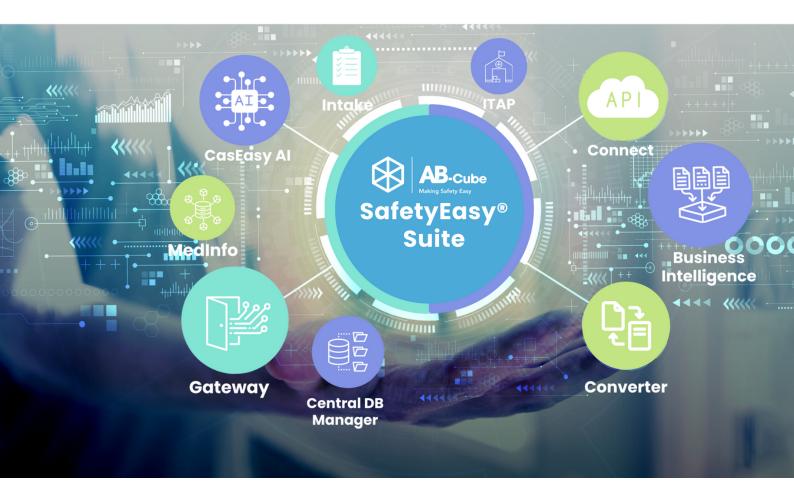


SAFETYEASY® SUITE

TRUSTED LIFE SCIENCES CLOUD SOFTWARE

Discover the industry's most efficient multivigilance safety database





Flexible & scalable

Global multivigilance needs at every scale - from 0 to 1M cases



Go-live in 2 weeks

Lightning-quick data migration by proven experts: 99.9% error-free



Automated efficiency

Narrative template automation reduces manual effort by 50%



Low total opex

Low ongoing operating costs and minimal resources required

Discover the power and efficiency of an Al-powered multivigilance solution.

Ensure effortless global vigilance operations in one platform.

AB CUBE: YOUR SAFETY PARTNER

AB Cube is the trusted partner for pharmaceutical laboratories, CROs, pharmaceutical solution organizations and health authorities worldwide. Our solution SafetyEasy® Suite is the industry's best-inclass multivigilance safety database, delivering - in one unified platform - effortless pharmacovigilance, materiovigilance, cosmetovigilance and nutrivigilance.

As a pioneer of SaaS vigilance applications, AB Cube provides an intuitive, agile and fully compliant solution adapted to your organizational needs. Thanks to our dedicated in-house team, AB Cube offers responsive, personalized support and training to optimize your vigilance strategy and day-to-day operations.

SAFETYEASY® SUITE



Flexible & Scalable

Whatever your company size, AB Cube can support your organization and adaptably scale as your business operations grow to a limitless number of users globally. With full price transparency, we promise no hidden costs.



Security

Patient safety is at the center of our solution development. We guarantee data confidentiality, integrity and security.



Effortless compliance

As your trusted software vendor, AB Cube provides a pre-validated application in compliance with GAMP5 and FDA CFR21 part 11 standards, ensuring minimum additional validation effort. Up-to-date validation dossiers and automatic system updates keep your team compliant with the latest drug safety regulations.



Seamless migration

Lightning-quick data migration delivered by proven experts, with full onboarding to support your team with change management. Benefit from easy learning and user adoption thanks to intuitive application interfaces, comprehensive user guides, and e-learning.



🦃 Smart automation

SafetyEasy® integrates an intuitive user interface, intelligent automation to streamline day-to-day activities, and reduced manual effort thanks to narrative templates. Accelerate reporting processes with our reportability matrix and one-click submission of your regulatory reports.

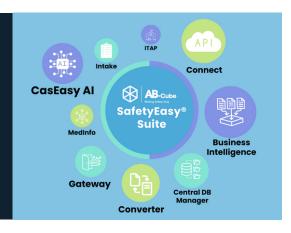


(1) Continuous innovation

Our customers benefit immediately from latest system upgrades and product enhancements - at no extra cost.

AB Cube Galaxy: next-generation vigilance applications

Our AB Cube Galaxy enhances SafetyEasy® capabilities, powering your vigilance operations with easy systems integration, cognitive automation for case processing, and 360° vision of your data.





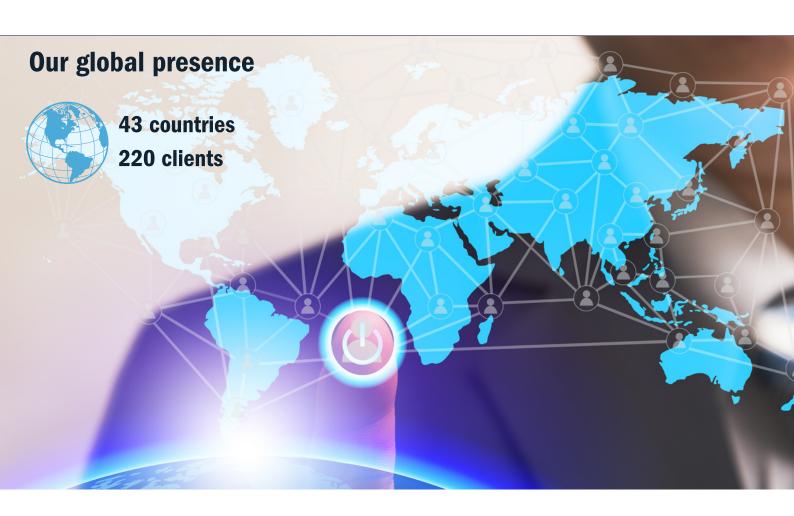
SAFETYEASY® KEY FEATURES

		Included
Multivigilance	Pharmacovigilance, Materiovigilance, Cosmetovigilance, Nutrivigilance in one application – with differentiated vigilance specific functions	~
	Management of several vigilances within same ICSR (eg. Mixed PV-MD cases, combination product cases)	~
Report generation	CIOMS I, Medwatch	~
	XML E2B(R2), E2B(R3) import/export & XML HL7, XML MIR export	~
	Generation of all Periodic Safety Reports appendices (PBRER ST, PSUR LL, DSUR ST & LL, PADER)	~
	Automatic mail generation	~
	Signal detection modules: PPR, ROR & Qualitative	~
Regulatory compliance	MedDRA coding (2 updates / year), IMDRF	~
	Strict GDPR	~
	FDA Combination products-compliant	~
	Auto anonymization (for Transfers Outside of the EU)	~
	Duplicate check	~
	XEVMPD integration	✓
	Integration of MedDRA SMQs in queries to facilitate regulatory reports assessments	~
Administration	Superior administrator functionality	✓
	Full customization in administration module: complete workflow & reporting rules per product, fields & flags management, flexibility of user role definition & permits	~
	Data entry display in multiple languages	~
Data entry	Customizable case narrative & sender's comment template	✓
	Autolabelling	✓
	Automatic submission and dispatch	~
	Mail reminders and alerts	✓
	Free MedDRA re-coding	✓
Security	Hosting on HDS/HIPAA-compliant servers	✓
	WAF	✓
	Annual software security audits & quarterly vulnerability scans	✓
	Back-ups	✓
	High availability & business continuity plan	✓
	Hosted in Europe	~

Ready to explore more?

Book a demo with AB Cube today

www.ab-cube.com/multivigilance



Trusted by industry leaders

















BIOCODEX

