SAFETYEASY® SUITE
TRUSTED LIFE SCIENCES CLOUD SOFTWARE

AB CUBE: YOUR CRO SAFETY PARTNER

AB Cube is the trusted partner for CROs globally. Our solution SafetyEasy® Suite is the industry's best-in-class 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, scalable and fully compliant solution adapted to your organizational needs, with training and responsive, personalized support from our dedicated team.

SAFETYEASY® SUITE: KEY BENEFITS

Flexible & Scalable

Whatever your CRO size, AB Cube can support your organization and adaptably scale as your number of sponsors/vendors grow. Our business model is transparent and based on the number of annual cases you process, regardless of the number of users.

Security

To deliver the highest security and data privacy, we have created a technical architecture dedicated to supporting CROs. **SupraSchema** offers the best of both worlds – familiar access to our best-in-class SafetyEasy® software on a multi-tenant basis, with secure, single tenant databases provided for each of your customers.

Ease of database management

Query all databases simultaneously (for example, obtaining KPIs), manage multiple system users from one dashboard, and organise user configuration - including settings and workflow - in a single portal.

Smart automation

SafetyEasy® integrates basic and cognitive automation to streamline day-to-day activities. Reduce manual case intake with narrative template generation, and speed reporting thanks to our reportability matrix and automatic report submission.

Intuitive

Our intuitive software interface and training offered during the onboarding allows for immediate ease of use.

Effortless compliance

Validated to 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.

SAFETYEASY® SUITE: KEY FEATURES

Category	Feature	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 today

www.ab-cube.com/multivigilance

Trusted by industry leaders

aixial GROUP

cencora
PharmaLex

VCLS

PSI