AB-Cube
Making Safety Easy

Making Safety Easy

Decoding SafetyEasy® Suite, multivigilance management solution

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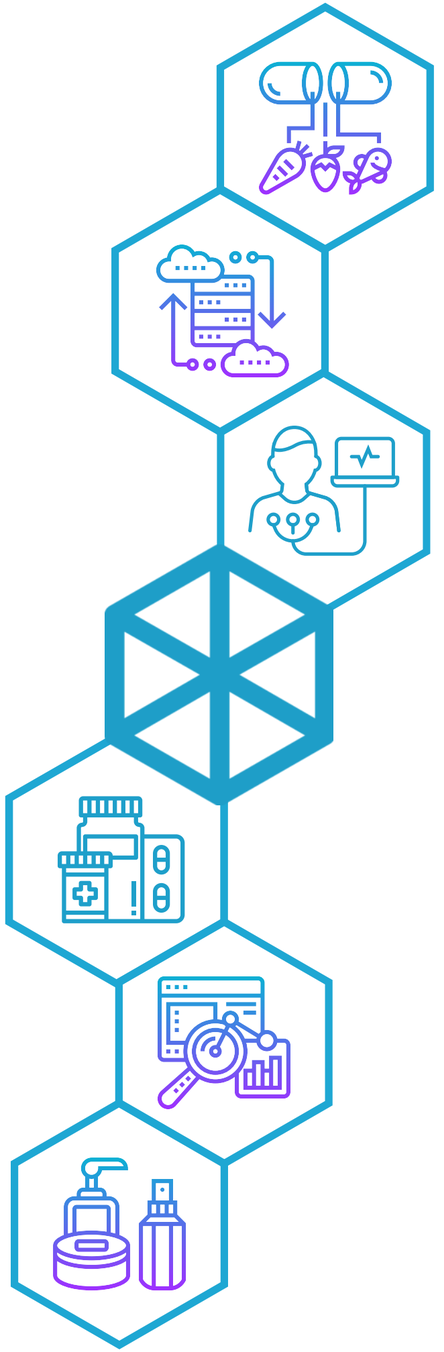
May 2021



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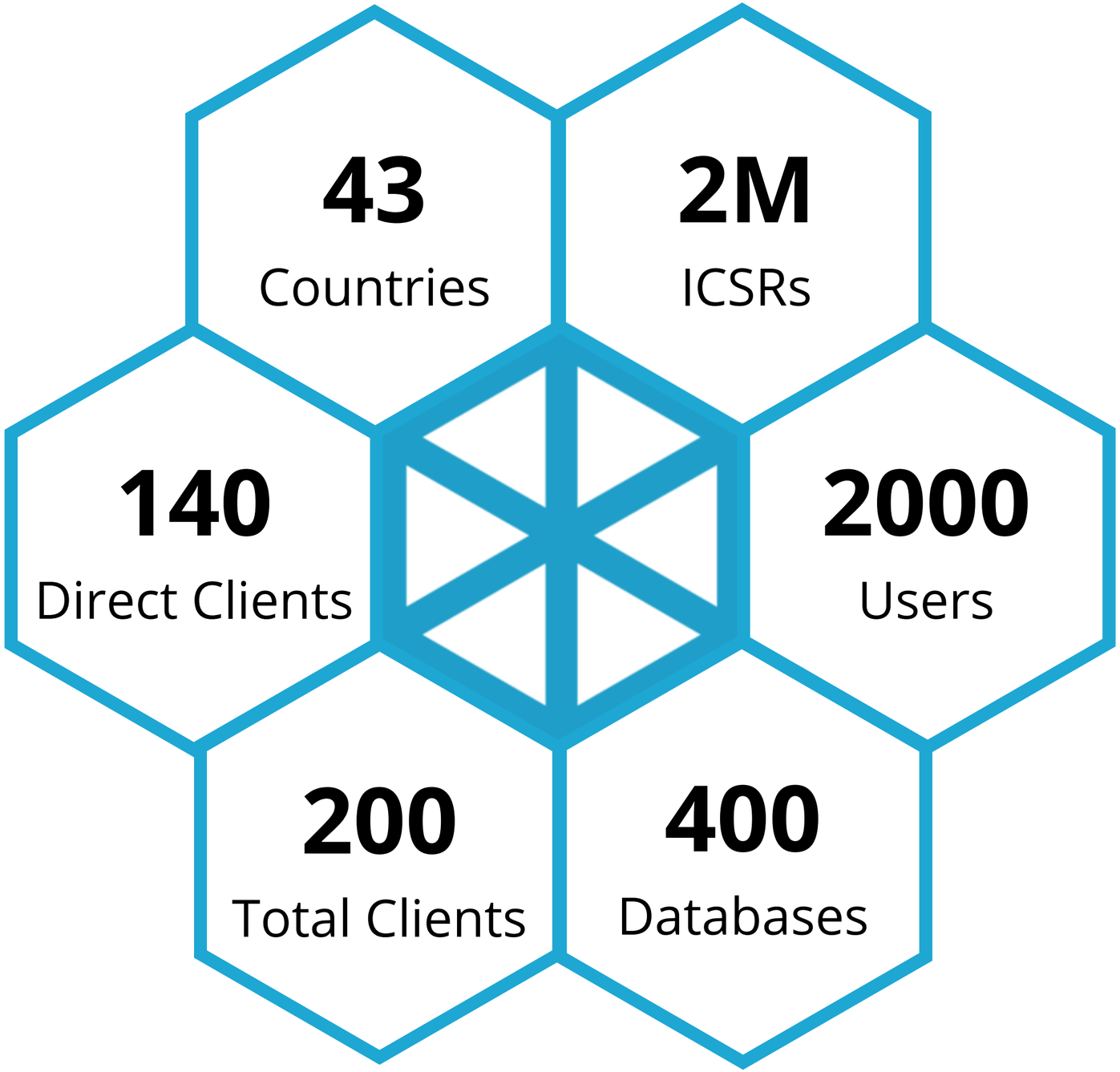
Making Safety Easy

15 Years

towards

Making Safety Easy



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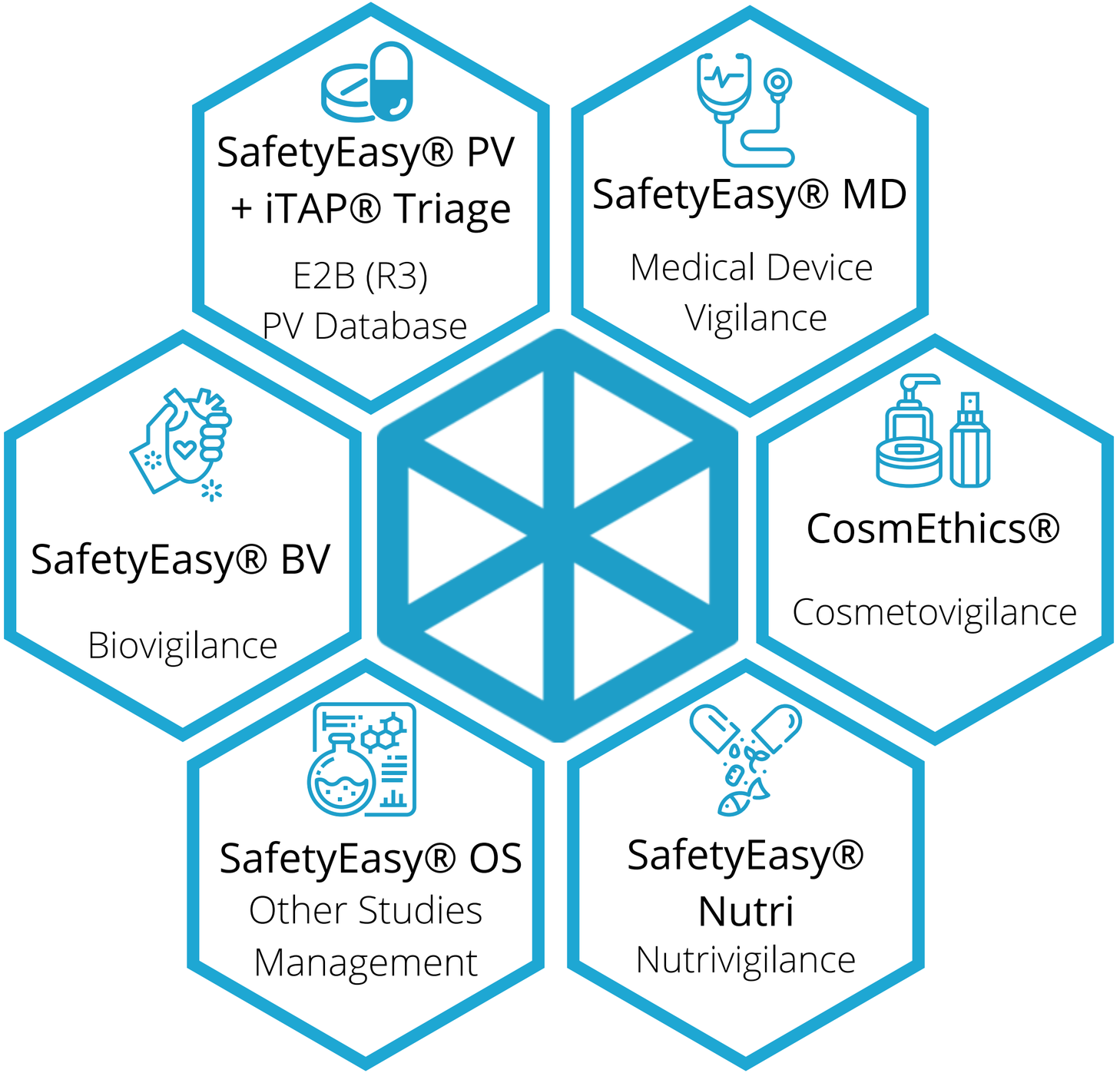
SafetyEasy® Suite

Multivigilance Management Solution

Making Multivigilance Easy



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Tools

for Automation
& Management

iTAP Triage

Triage Automation Tool

MigEasy

Internal Tool for Automated Migration

SafetyEasy MI

Medical Information Management

SafetyEasy® Suite - Terminology

Vigilance

Univigilance platforms like SafetyEasy® PV, SafetyEasy® MD, CosmEthics®, SafetyEasy® Nutri, SafetyEasy® BV, SafetyEasy® OS

Solution

SafetyEasy® Suite, the complete multivigilance management solution
OR
More than one database, e.g. SafetyEasy® PV + CosmEthics® = SafetyEasy® Suite

Tools

SafetyEasy® MI, iTAP® - Triage, MigEasy® (Internal tool for automated migration)

Environment

For CROs, each of their clients will have an environment to work on.
Each environment may have vigilance or solution.

We're Trusted by

L'ORÉAL

ansm
Agence nationale de sécurité du médicament et des produits de santé

VigiMedsafe
Pharmacovigilance and beyond

ProductLife GROUP

CADILA PHARMACEUTICALS LIMITED

Air Liquide HEALTHCARE

Grindex

GROUPE CLARINS

PHARMINVENT

GPSC
Making progress for your health

Universal Medica
A division of Universal Medica Group

PHARMALEX

macopharma
DESIGNED FOR LIFE

BIOCODEX
France

STRAGEN

addmedica

Debiopharm Group
WE DEVELOP FOR PATIENTS

VCLS
Voisin Consulting Life Sciences

VIGIPHARM
La vigilance des produits de santé à votre service

EXPANSCIENCE LABORATOIRES

mundipharma

SERB
SPECIALTY PHARMACEUTICALS

NORDIC PHARMA

Ethypharm

AXPHARMA

INNOTHERA

septodont

SYMOGEN

viglya

DD CRO SMS oncology

SMB
Innovator in Galenics

aixial
AN ALTEN COMPANY

Pioneers of SaaS

Cloud-based vigilance database since 2006

Secure

- Hosted by HDS compliant server
- 2 hours disaster recovery plan (DRP)
- Business continuity plan
- Regular intrusion tests

Cloud

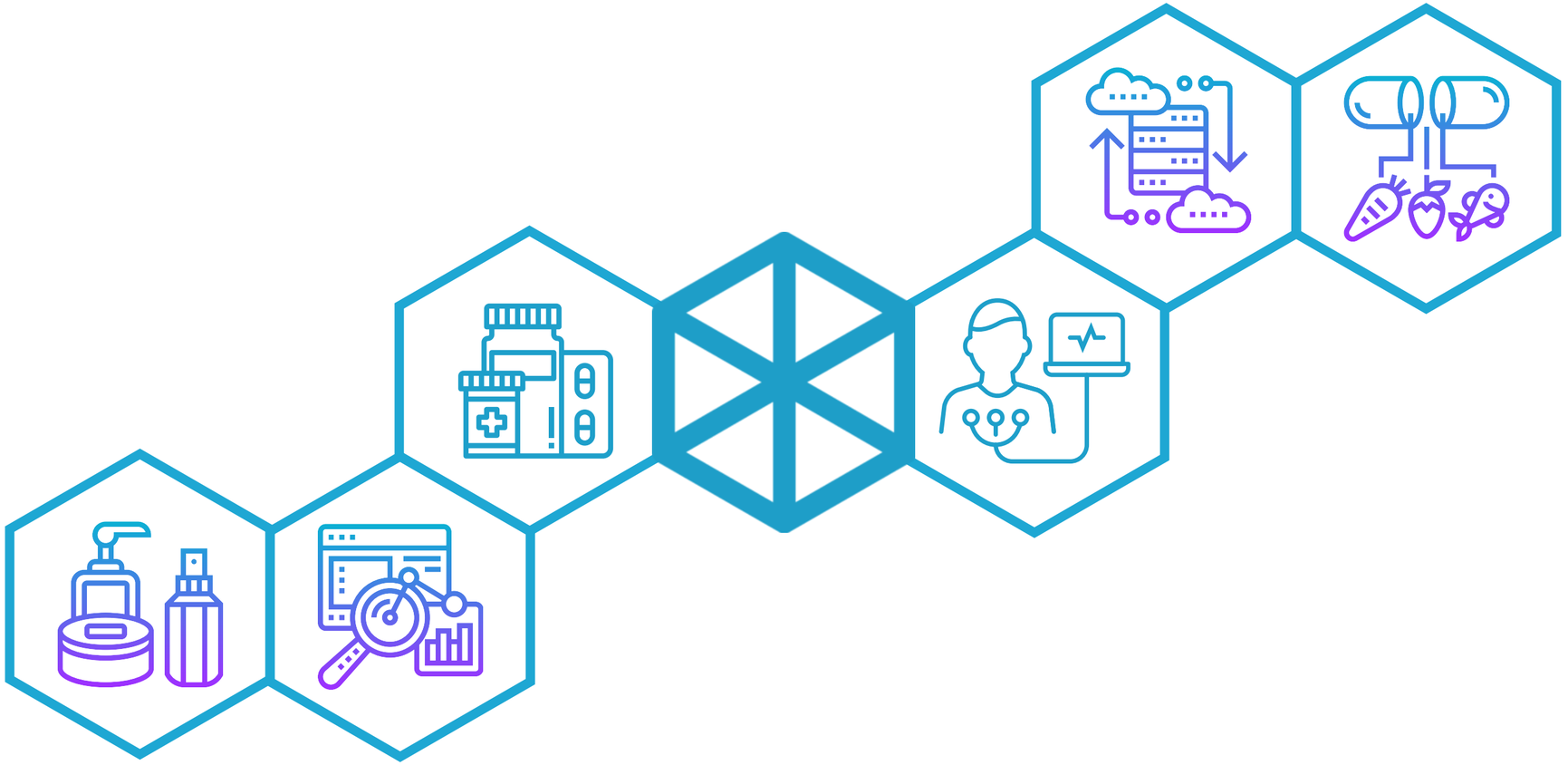
- Easily implemented in 2 weeks
- Private cloud available on demand
- Easily adopted with training & eLearning

Compliant

- Fully compliant (FDA 21 CFR part 11, EU GMP Annex 11)
- Full validation dossier (IQ, OQ, PQ), in line with GAMP 5

Efficient

- Edit reports in the blink of an eye
- Increase efficiency of your global safety operations with faster and agile solution



SafetyEasy® Suite

Making Multivigilance Easy

Combination Products.

Multivigilance.

Global Compliance.

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Making Safety Easy

SafetyEasy® Suite
Multivigilance Management Solution

Increase operational efficiency across the globe

- Centralised database for all your products
- Advanced report generation: All cases related to a product with different regulatory status in different countries in a single report
- Faster data entry and case management: No double data entry and reconciliation
- Centralised search for data and cases
- Same level of automation for all families
- Only one validation dossier and one database to maintain

Seamless automation

Integrates with your existing vigilance processes

Leverage the power of **Automation**

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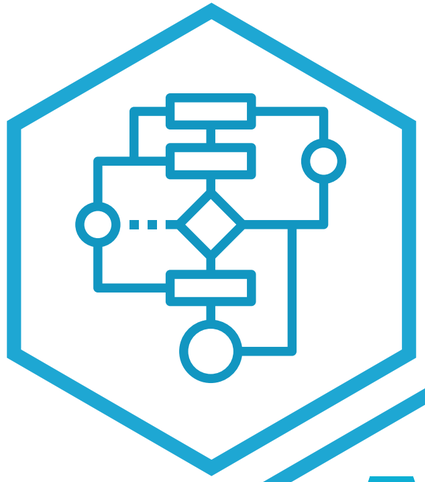

Basic Automation

Automated workflow management

Robotic Process

Automated case intake, triage

Cognitive Automation

Natural language processing linked with MedDRA and WHODD

Quick & Compliant

Data Entry

Safe, One Click

Submission

Powerful &
Customisable

Reporting

3 Steps to Making Safety Easy

We're making data privacy easy for healthcare

SafetyEasy® MI

Medical Information Management

SafetyEasy® MI

Medical Information Management Software

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What?

- Used as a hub to collect all the information one needs or is aware of.
- Helps capture and qualify a file of MI to any type of quality, vigilance or customer claims.

Why?

- Complete control over the database and who can access it, unlike spreadsheets.
- Can be linked to all vigilances of SafetyEasy® Suite
- Create cases through SafetyEasy® MI in other databases accordingly.

SafetyEasy® MI

Medical Information Management Software

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Features & Functionalities

- MedDRA Integration.
- Possibility to code a drug and a medical device
- Advanced report generation modules (spreadsheets grouped by, pivot tables…)
- Can be linked to SafetyEasy® Suite
- Check duplicate
- Audit Trail
- Administration: workflow, user management, recalls and notifications…

SafetyEasy® MI

Medical Information Management Software

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Happy Clients

septodont

"We recommend SafetyEasy® for 3 main reasons,

1. **User-friendly** interface and **customisation** capability,
2. Ability of SafetyEasy® to **evolve and adapt** to the latest guidelines,
3. **Support** offered by AB Cube and the **responsiveness** of their team"

http://www.septodontusa.com/

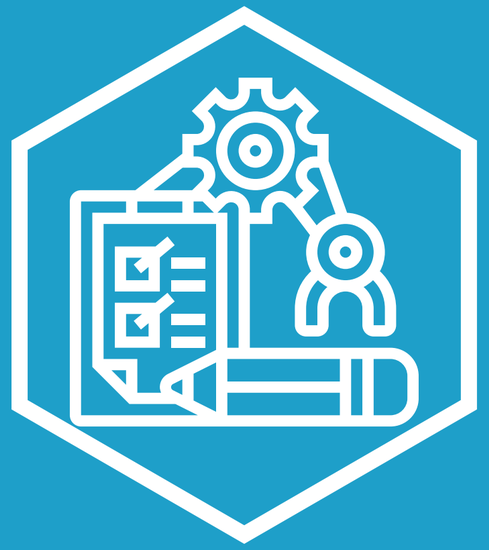
SMB
Innovator in Galenics

http://www.smblab.be/

Up to 85% more efficient ICSRs activities

Be inspection ready with

iTAP® – Triage



iTAP® – Triage

Customise.
Automate.
Track.

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Making Safety Easy

Triage

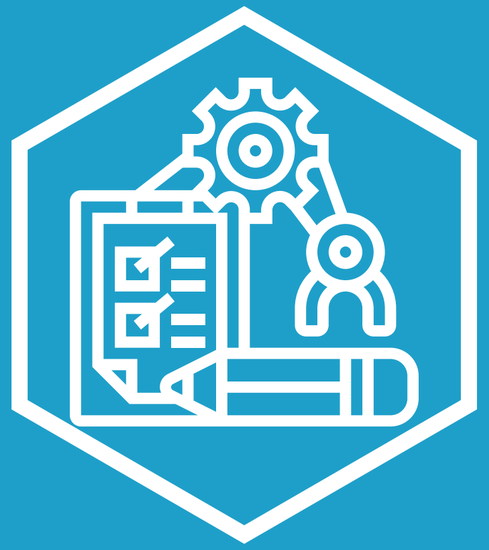
- Management of MLM / L2A / Partners' ICSRs
- Customizable filters for each product

Assessment

- Dedicated assessment space for each company
- Automatic Assessment based on chosen filters

Processing

- Tracking of all decisions in reports
- Integration to your safety database



iTAP® – Triage

Customise.
Automate.
Track.

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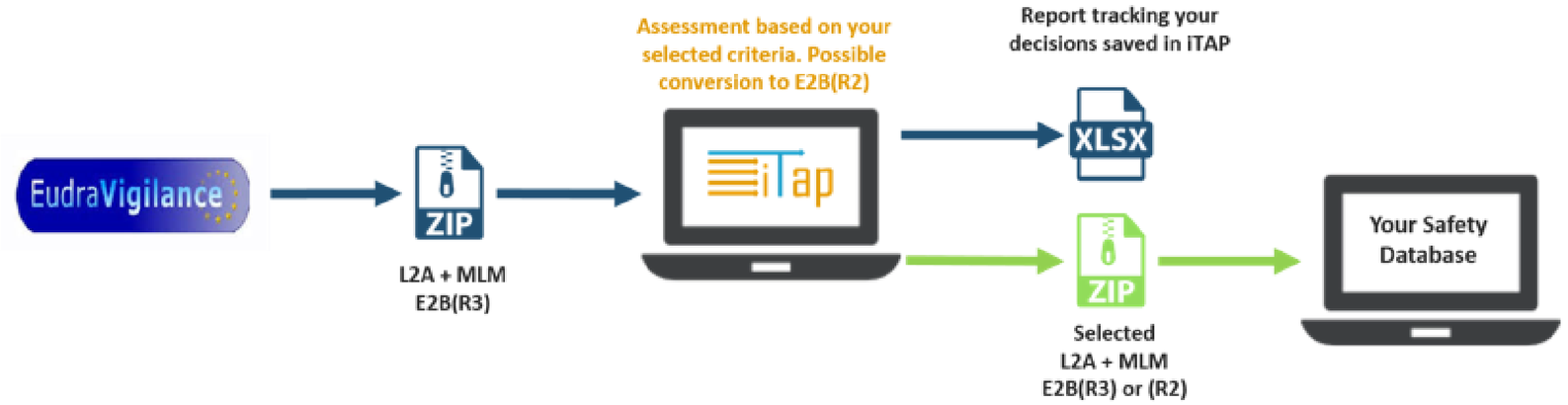
iTAP® (ICSR Triage Assessment & Processing)

- Import via batch, ICSRs will be injected in a SaaS zone (iTAP®)
- Filters can be managed by the users and/or administrators, where they have to be set up beforehand
- Possibility to filter all ICSRs' fields.
- Import of partner's cases
- Possibility to open the cases into iTAP® and check the information.
- Report is generated and available at all times in iTAP®
- Track all the decisions (imported or rejected cases), through an audit trail with the reason of the rejection.

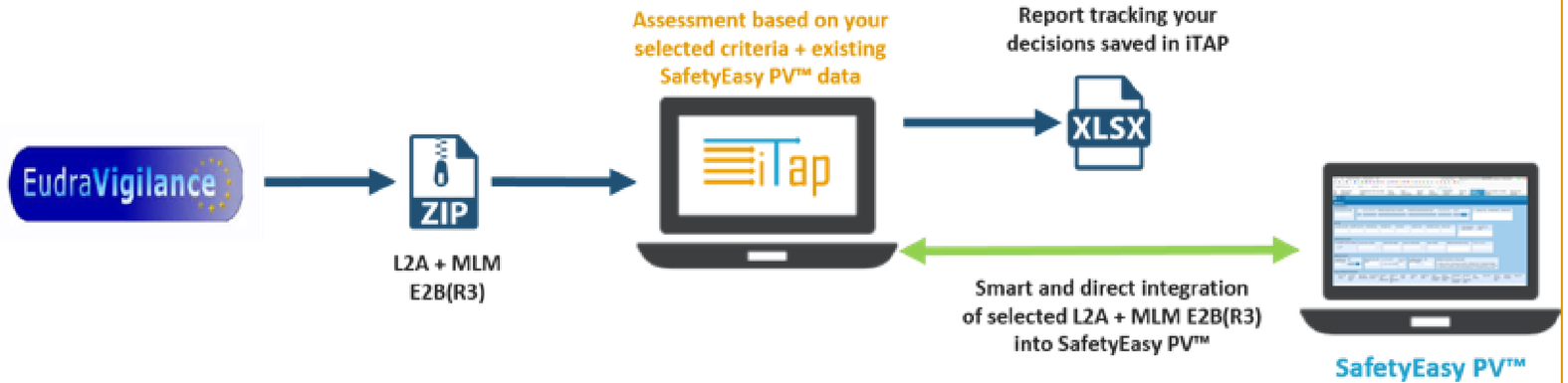
Multi Tenancy: One triage space per company within the same iTAP® tool

Other safety database users:



Single Tenancy: Integrated inside each SafetyEasy® Suite database

SafetyEasy PV™ users:



Benefits of iTAP® – Triage

- **High ROI:** Time saving through automation of activities
- **Automation** prevents human mistakes
- **Structuring:** Helps you structure your workflow
- **Fully Reliable:** All filters are maintained by administrators
- **Measures and stats:** Helps you keep record of your activity
- **Fully Compliant** (FDA 21 CFR part 11, European GDPR etc.
- **Inspection Ready!** All decisions are fully tracked and saved in reports

SafetyEasy® Suite

The Specialist of Choice for CROs

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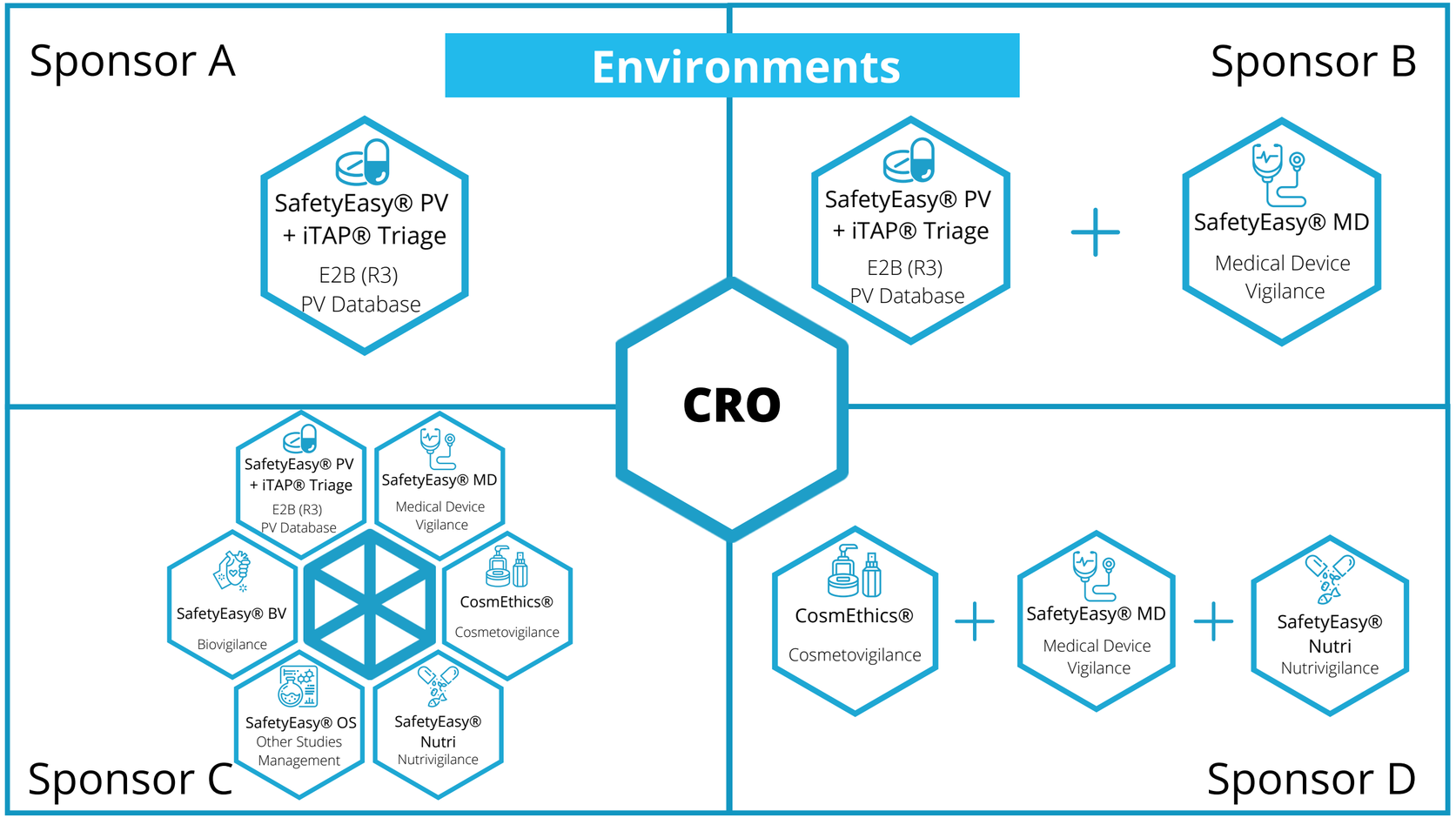
Single Tenancy Databases

One environment for each sponsor



- Adapts to your business processes with each client
- Guarantees data privacy, separation enables easy management of data for each client
- Give access of the database to your clients

Business & Contract

High ROI: Save time & money

- Centralized administration tools
- Automated activity reports
- Gateway for easy submission of cases

Terms and payment options designed for CROs

- Full contractual flexibility: **Can open or close database anytime**
- One implementation charge: Regardless of the number of databases

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No hidden costs

Transparent terms and conditions since Day 1

What's included in your **Licence**

AB-Cube
Making Safety Easy

- All features and functionalities
- Latest regulatory compliance
- **Unlimited number of users**
- Quarterly upgrades for no extra cost
- Online access to documents
- Healthcare certified hosting
- Standard validation dossier
- Support through tickets

Thank you for your attention

Please feel free to get in touch for any questions and clarifications.

We're Making Safety Easy

AB-Cube
Making Safety Easy

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