Safety Database

Making pharmacovigilance easier

Abacus Company

MANAGE YOUR PHARMACOVIGILANCE DATA

Collect, store, manage, report and analyze adverse event data in a unique safety database. Import clinical trials and post marketing surveillance data, of drugs and devices, in XML or HL7 file format.

SIMPLIFY YOUR PHARMACOVIGILANCE ACTIVITIES

Selective Import

Reports

Search for duplicates

Analysis

Message system

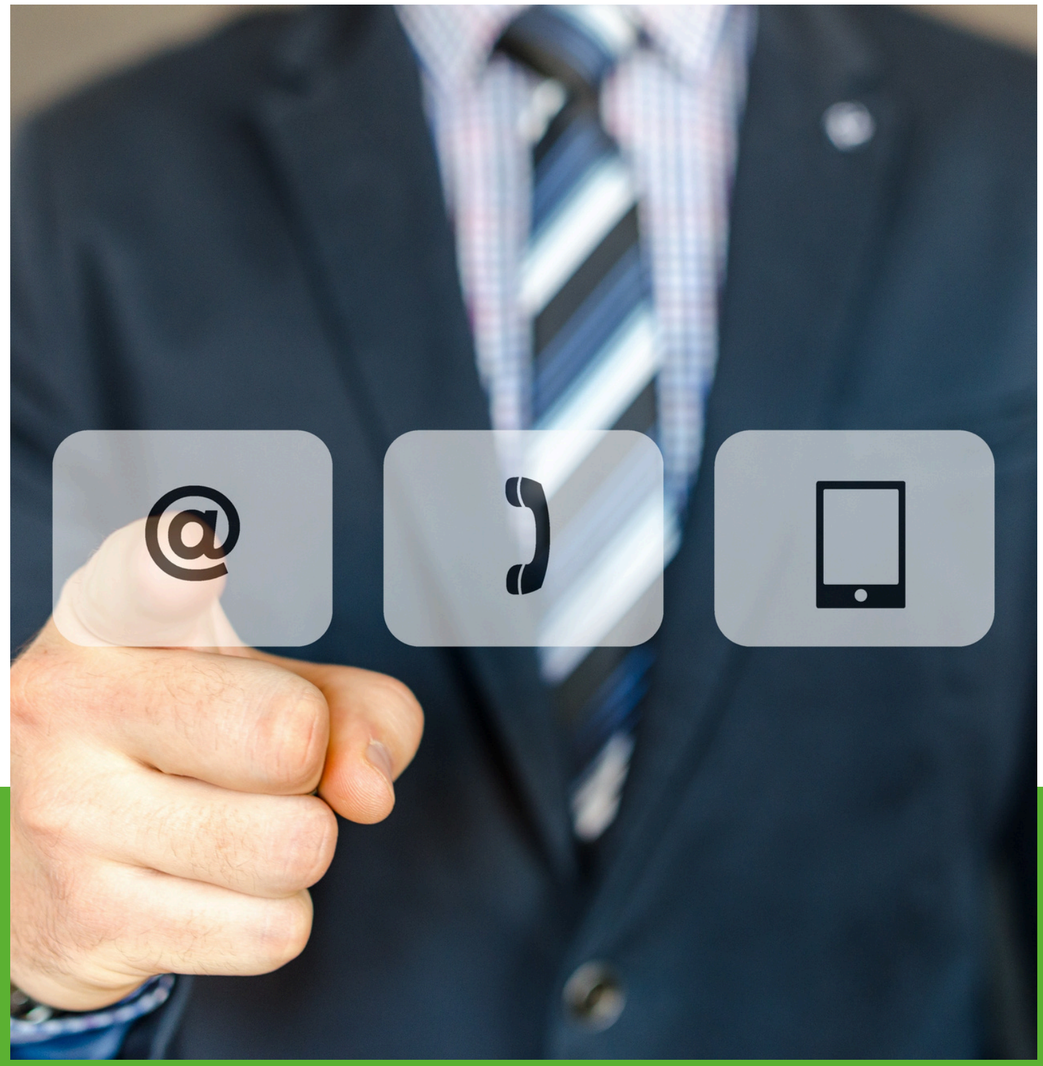
To-do / Deadlines

SELECTIVE IMPORT

Define which cases to import performing the relative triage and evaluating the applicability, thanks to the preview of the most meaningful ICSR information

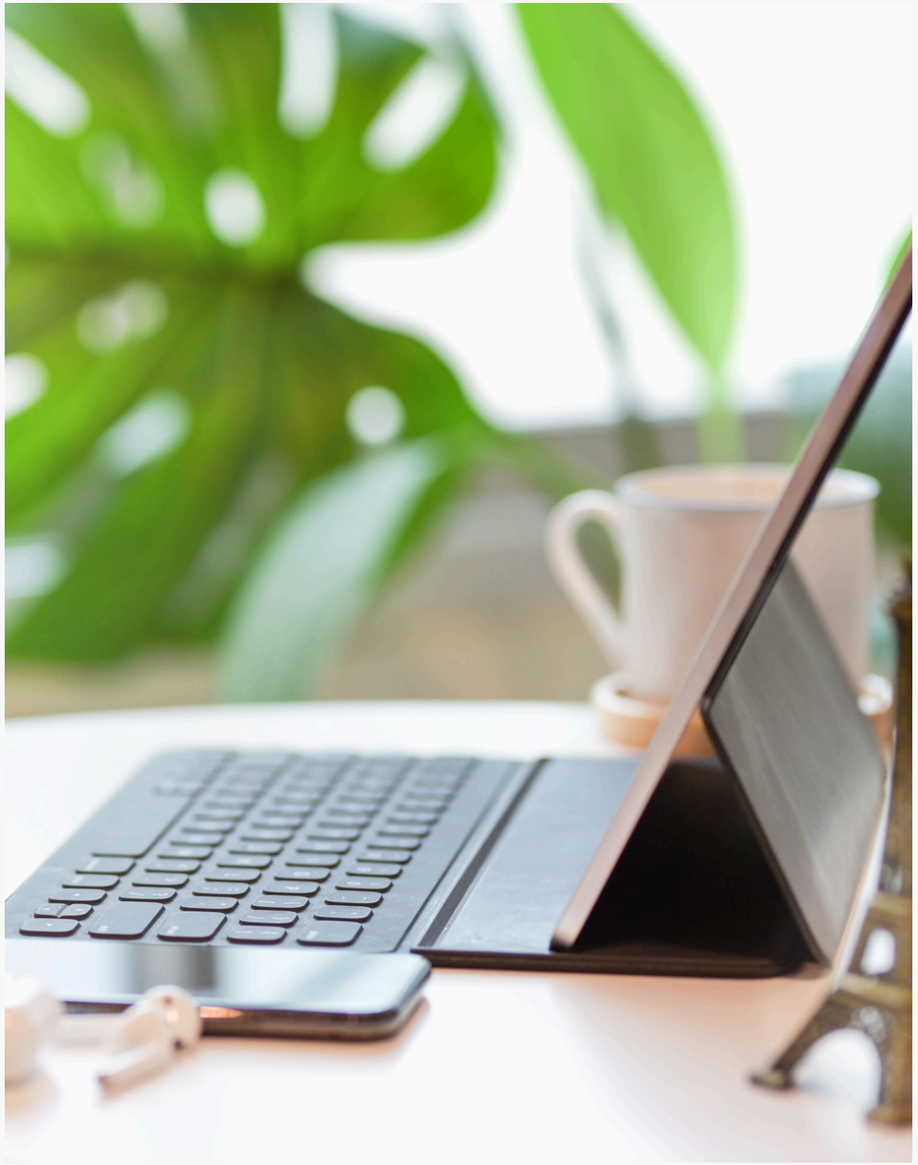
MESSAGE SYSTEM

Send automatically reminder messages linked to expiring/expired cases or to specific activities and customize templates based on the receivers



DEADLINES

Keep track of your regulatory deadilines and be noticed about upcoming dates



REPORTS

Perform all regulatory reports and many others

- CIOMS
- Pregnancy form
- PSUR (line listing, summary tabulation, work sharing)
- PBRER (cumulative Adr(s))
- DSUR (line listing, summary tabulation)
- Standard MedDRA Queries (line listing, summary tabulation)
- MIR
- PADER
- MedWatch3500A
- Quality Check Report
- Cover report
- Customizable listings for inspective purposes and reconciliation

ANALYSIS

Integration with Business Intelligence

Run thorough analyses such as

- Signal Detection
- Comparison among selected temporal intervals
- Quantitative analysis with possibility to view detail on single case for qualitative examination
- Customized line listings
- KPI analysis to monitor the ICSRs processing time

SCALABLE

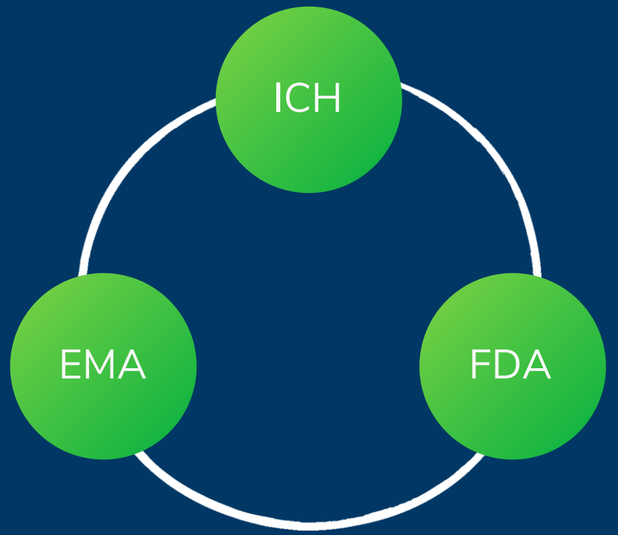
Adapt the database according to your company business. Choose the package and the optional modules more suitable for you

CUSTOMIZABLE

Customize your database on your needs and on your company procedures. Everything from the user parametrization to the workflow can be personalized

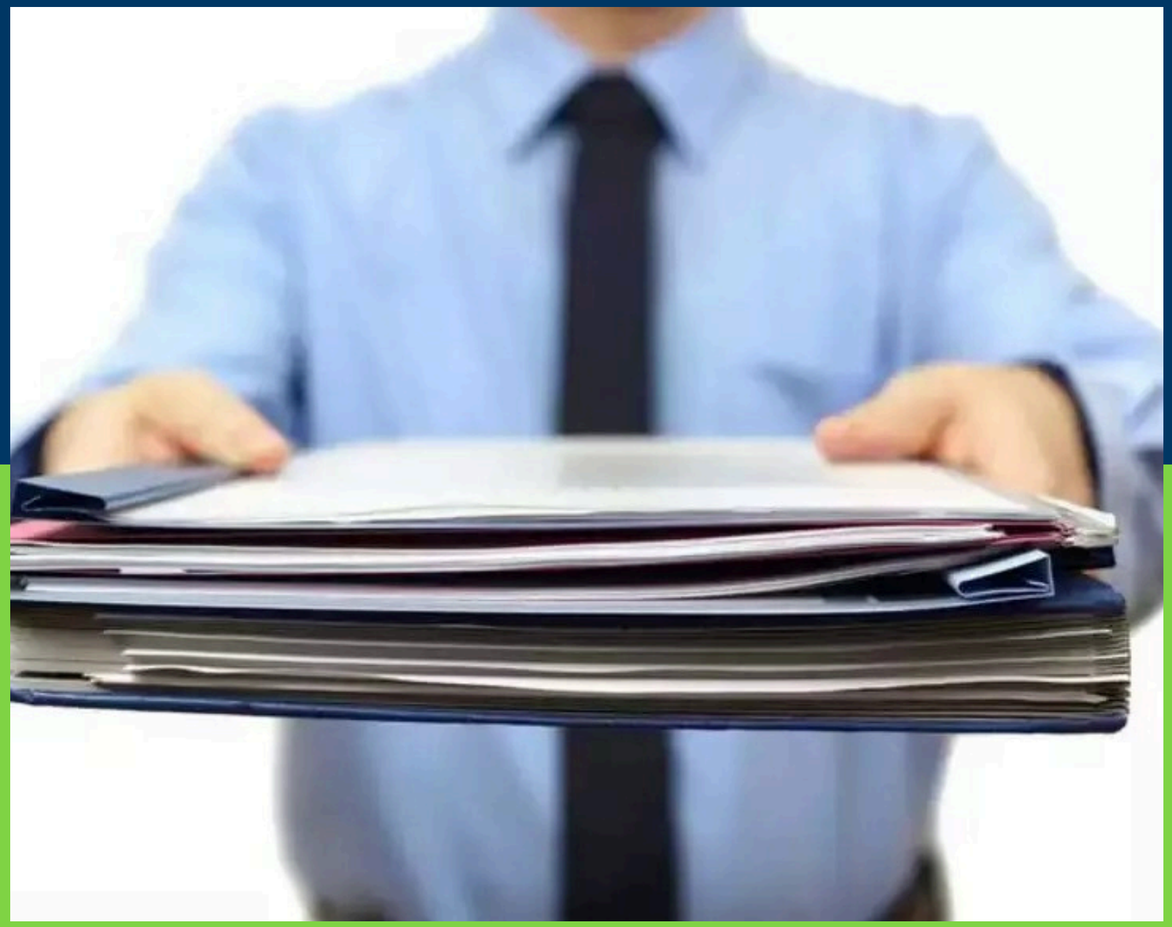
COMPLIANT

Supply your company with
a safety database compliant to the requirements of



VALIDATED

Easily obtain a consistent
Computer System Validation
with **SafetyDrugs Validation Kit**,
specially formulated to ensure
a quick and a cost effective start-up,
in accordance to GAMP5 guidelines



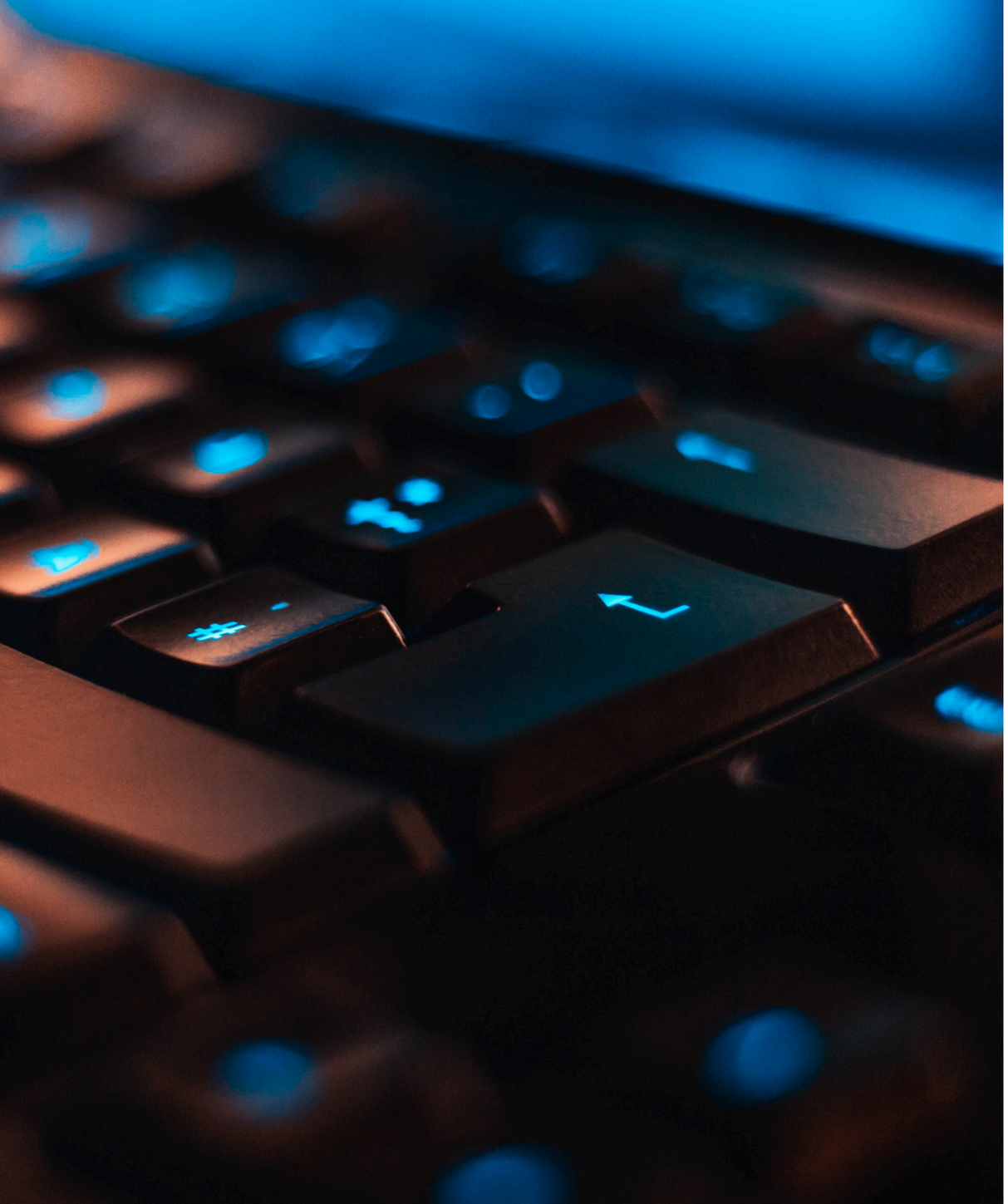
SaaS

Rent the database and avoid your company
to invest in hardware, maintenance
and security measures.
Moreover, the backup and
the disaster recovery service is included

Available in

ON-PREMISES

Or purchase the database and install it on
the company server,
to have data physically stored in the firm



SECURE

Keep you data safe.
With the SaaS mode data are stored in Oracle datacentres.
The protection is garanted at various levels

SCHEDULE A DEMO NOW

Or contact us for every question

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