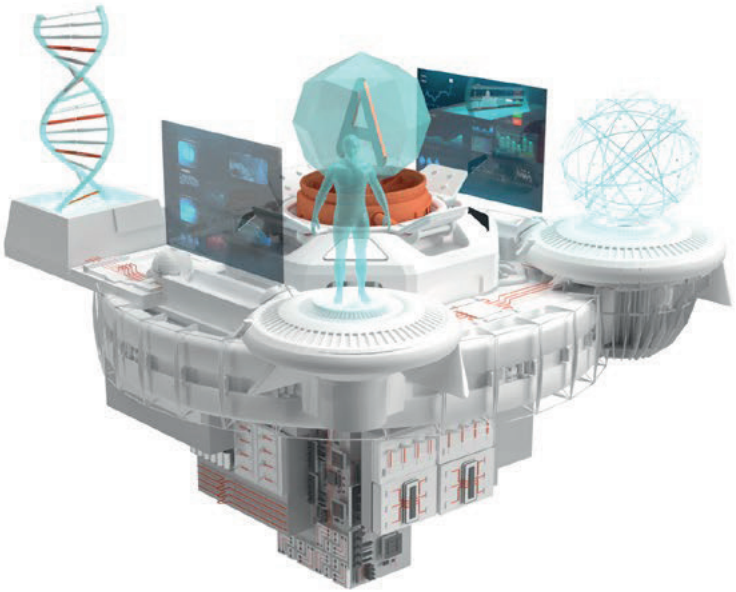
nubilaria ACTide

The complete eClinical Ecosystem and Data Management Solutions provided by Nubilaria

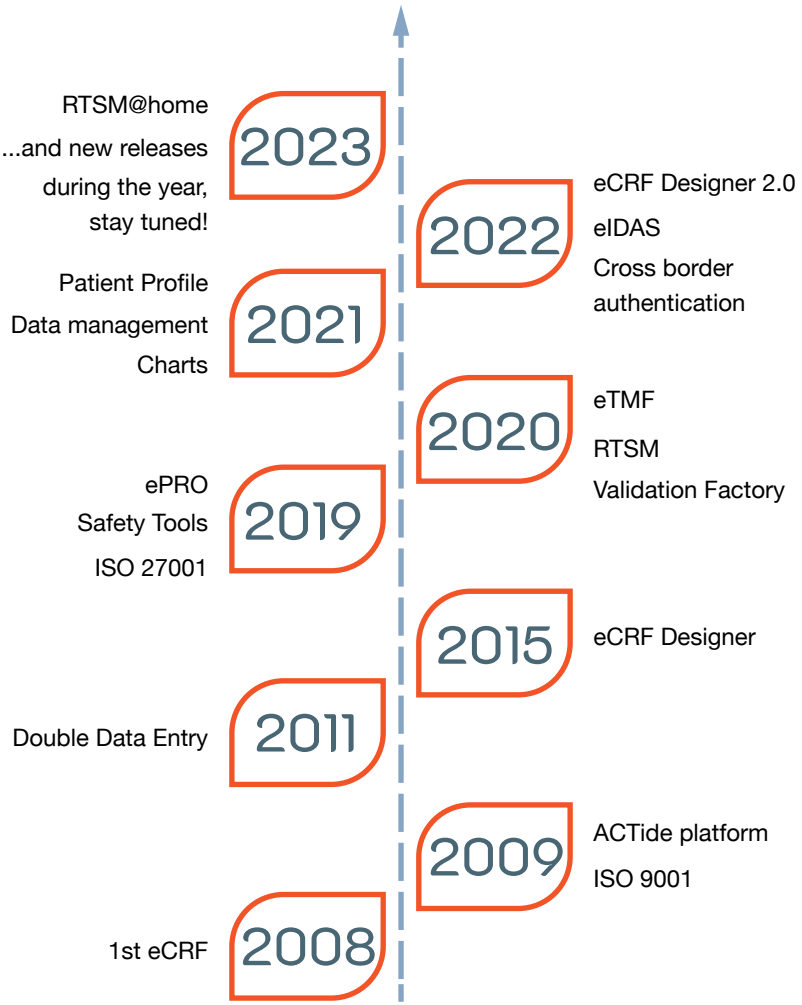


Our History

Nubilaria is a Solution Provider with an in-depth expertise in Data Management. Early experiences arise in the Banking Reference Data market in the early 2000s. Since 2008 we have been committed to our second line of business: clinical research. We developed our proprietary Data Management platform - ACTide® - which embraces a broad ecosystem of modules including:

- Electronic Data Capture (EDC).
- Data Cleaning.
- Data Retrieval.
- Clinical Data Management.

Over the years, ACTide has evolved with the addition of new modules and functionality so to cover more and more clinical trial-related processes.



We believe in tailored solutions live in weeks instead of months.

www.actide.com

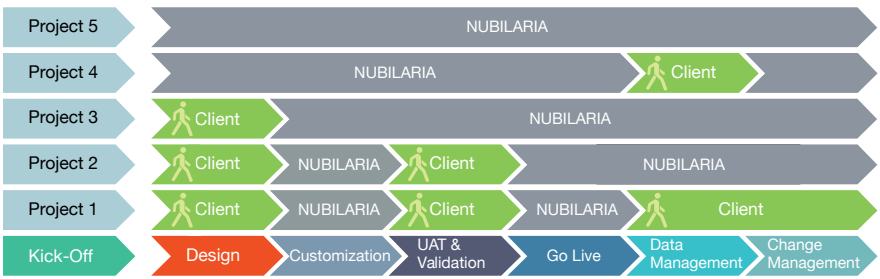
Collaborative Approach

We aim to consider customers more as partners than as mere buyers of our solutions.
We establish long-lasting relationships (customer turnover rate of less than 3%) and settle a flexible collaborative approach.
We give them the freedom to choose the level of involvement in the implementation workflow of their projects.

Once methodologies are actively shared, it's possible to achieve different service configurations on a per-study basis to balance activity peaks, budgets and/or prioritize mission-critical projects.

At the 2 ends we have:
Tactical in-sourcing rather than out-sourcing. Perform in-house as much as you can. Leverage the efficiency that you gain from the complete control over the configuration process.
Gain Flexibility with the freedom of defining the desired level of in-sourcing on a per-study basis.

Customer is free to choose any In-Between Approach, jump in the workflow when they decide.



ACTide ecosystem

09 - RTSM

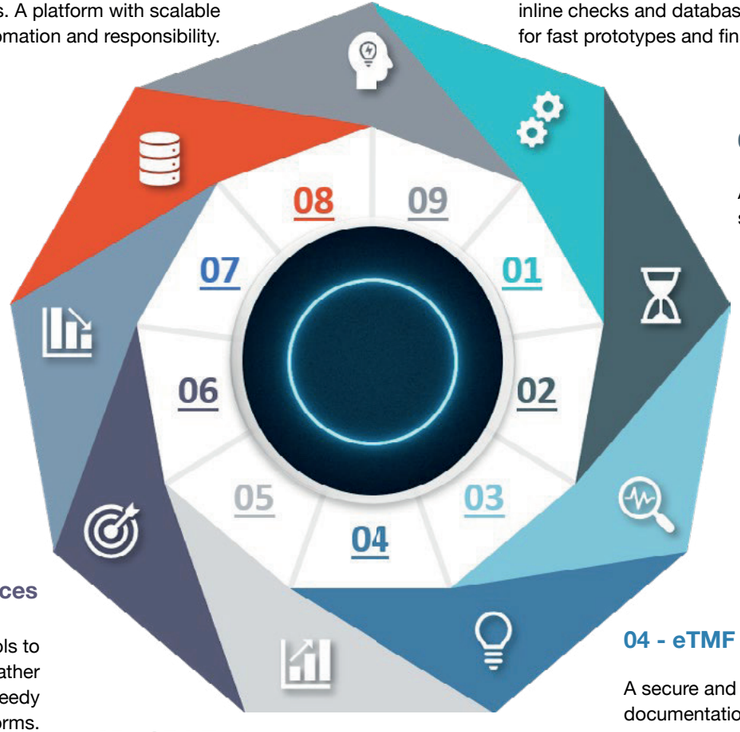
A comprehensive tool to manage randomizations and clinical trial supplies. A platform with scalable complexity levels of automation and responsibility.

01 - Designer

A powerful console to help you create the latest eCRF layout, inline checks and database structure or re-use archived ones for fast prototypes and finalized environments.

08 - Project Management Tools

A new paradigm for data management that delivers hands-on ability to mantain tight and responsive control over the study data (e.g. charts, KPIs, etc).



02 - eCRF

A flexible, role-based data capture system to safely collect study data in its compliant and validated database.

07 - Safety Tool

A fully configurable reporting system to deliver an intuitive insight of how patient data evolve over time.

03 - ePRO

A web-based module to capture eDiaries and questionnaires data within the same database of the eCRF with the convenience of using your own device of choice.

06 - Data Management Tools & Services

A revolutionary set of tools to allow data controls to be set and run at any time in the background rather than on the eCRF where Investigators need speedy and simple forms.

04 - eTMF

A secure and practical access point for TMF study documentation, supporting all essential document processes and reducing TMF management timelines, costs and risks.

05 - CRA Tools

A robust set of tools to centrally verify study data with ease, from multiple points of view and even remotely.

Designer

Powerful console to configure your study:

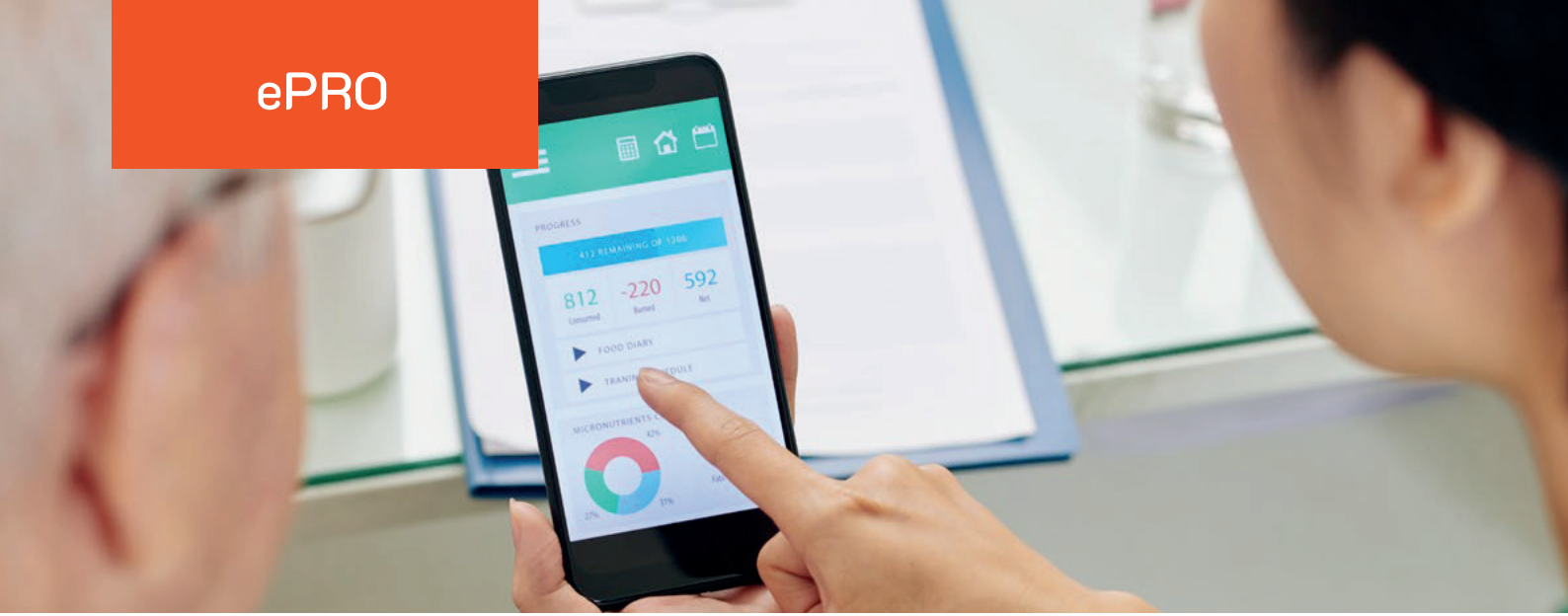
- Create the latest eCRF layout, inline checks and database structure.
- Unlimited release per each study.
- Unlimited number and size of eCRF archives.
- Unlimited & free eCRFs per each dashboard.
- Speed up prototypes as well as finalized versions for early go-live.
- Configure questionnaires and diaries.

eCRF

Full state-of-the-art EDC system:

- Standard and customized user profiles.
- Alerts and notifications system.
- Online audit trails.
- Monitoring & SDV tools.
- Automatic clarifications.
- Real-time data exports.
- **Unlimited users and sites.**
- Document sharing within study/site crew(s).
- Pre-loaded laboratory ranges.

ePRO



Fully featured mobile EDC solution:

- Login with username and password (or PIN), face-detection and fingerprint.
- Responsive design capable to automatically adapt its content to any device.
- Upload images and files from both the device camera and internal file system.
- Deliver on-device notifications.
- Multilingual interface.
- Store data directly in the eCRF database.

eTMF

Complete eTMF system for your studies:

- Online h24x7x365.
- Drug Information Association (DIA) TMF Reference Model natively compliant.
- Automatic backups.
- Complete, compliant and clear audit trail.
- Placeholders.
- Unlimited number of releases per document.
- Tags.
- Standard and customized reports.
- Store all eTMF related emails directly into the database.

Available integrated to ACTide eCRF or as a stand-alone service.

CRA Tools

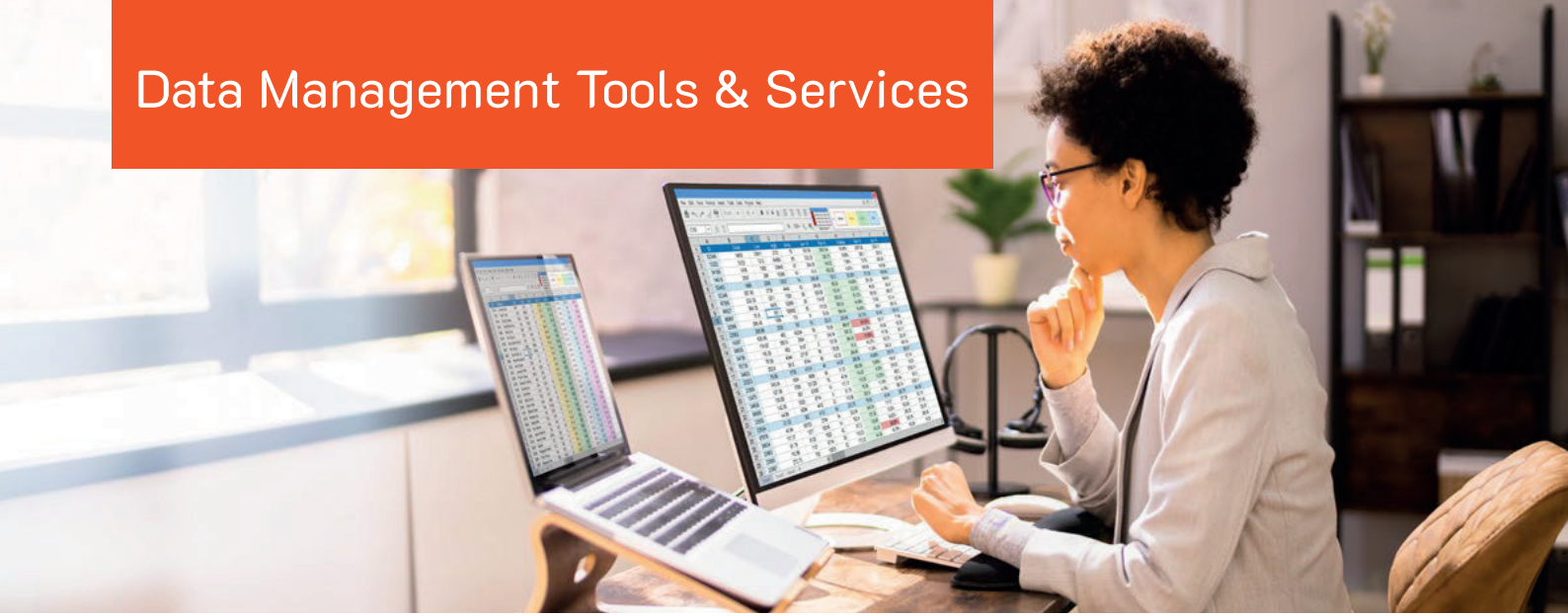
For Clinical Monitors.

Strengthen the quality of study data:

- Oversee data collection performances with advanced SDV tools.
- Track CRA's activity at sites.
- Open specific clarification requests on individual entry points.

www.actide.com

Data Management Tools & Services



For Data Managers & Study Coordinators.

Monitor data acquisition performances like:

- Enrollment.
- Response time to clarifications.
- SDV and % of data completion, etc.

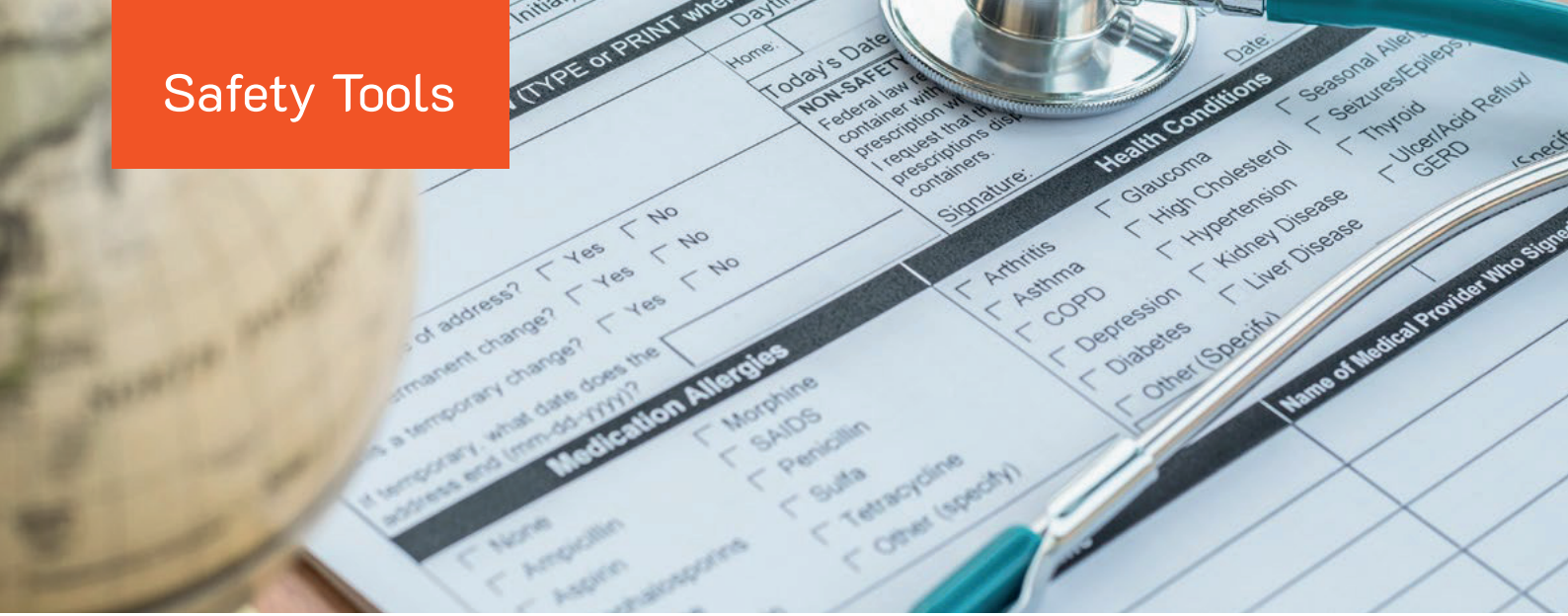
We provide:

- **Clinical data management.**
- Study level validation.
- Data integration and feed.
- Study migrations plus CDISC/CDASH compliant eCRFs.

Data managers supply **medical coding** with MedDRA, WHO Drug and ATC/ICD dictionaries.

Biostatisticians support you from **randomization** to TLGs for clinical study report and generation of **SDTM, ADaM & define.xml** files for FDA/PMDA submission.

Safety Tools



For Patient Data.

Complete study lifecycle:

- Structure unlimited report templates containing any data point present in the study database.
- Intercept new occurrences and archive scheduled data snapshots.
- Intercept data changes between data snapshots.
- Compare multiple data snapshots and populate an intuitive report with color-coded data for an easy reading of the entire lifecycle of each data entry value.

TOL, ADR, AE/SAE and more are now all safely archived and easily comparable in their progressive evolution.

www.actide.com

Project Management Tools

For Project Managers & Sponsors.

Keep under control key clinical indicators like:

- Protocol violations.
- Drug accountability & compliance.
- Form-specific listings, etc.

RTSM
(Randomization and Trial Supply Management)

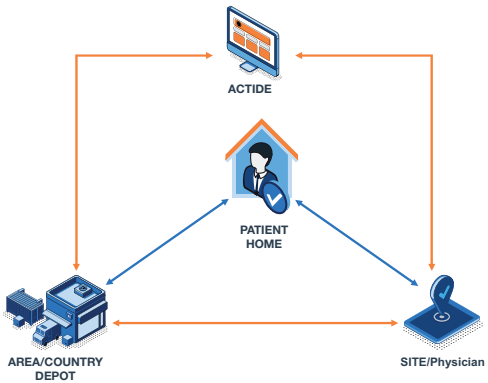
Two modules: RTSM@Site & RTSM@Home. Scalable complexity levels ready to meet the most complex protocol and business requirements.

Drug management of:

- Web randomization of patients.
- Dynamic Management of Investigator's prescriptions.
- Prescription-based Drug calculation with First Supply and Resupply to the patitent's home.
- Communications to depots and management interface.
- Automatic adjustment of re-supply threshold & related communications.
- Reporting and appropriate control/intervention interface.
- Support for uploading files to accompany shipments.

Drug tracking and reporting. Dashboards, listings, charts for all appropriate actors: sponsor, CRO, depots, centers, patients:

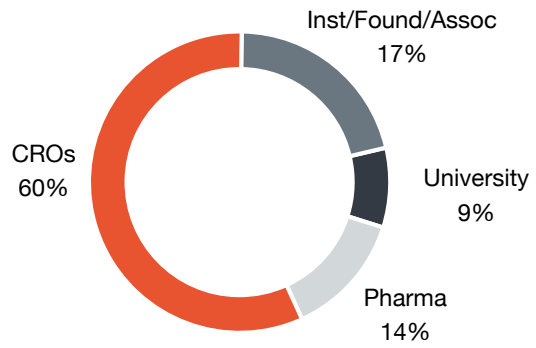
- Enrolled patients & their prescriptions.
- Tracking of «orders» according to prescriptions.
- Tracking of drug shipments status.
- Tracking of drug availability at patient's site.
- Tracking of drug consumption status.
- Tracking of unused drug return.



www.actide.com

Compliant & Certified ecosystem

Industry segment



Therapeutic Areas

Since the beginning, our ecosystem has been enabling real-time processes sustained by inspection-ready audit trails. ACTide has always been validated according to industry regulations:

- ICH / GCP - VICH/GCP
- FDA 21 CFR Part 11
- EU GMP Annex 11
- GDPR
- HIPAA
- CDISC Gold Member
- GAMP 5
- ISO / IEC 27001:2013
- ISO 9001:2015

Nubilaria Srl

Baluardo La Marmora, 13
28100 Novara, Italy

www.actide.com
Phone: +39 0321 612905
Email: info@actide.com