

AMEDON eCRF

GET WHAT YOU NEED

Our AMEDON eCRF solution allows you to decide: standardized data capture and/or individualized processes. With your personal contact person, the necessary features are defined to create and configure your AMEDON application based on your needs. Your protocol can be used directly for the setup of the eCRF and/or ePRO solution. At the same time, the project database and standard reports are set up automatically.

SAVING TIME WITH QUALIFIED RESULTS

Our eCRF is a self-explanatory solution with integrated data and process quality checks. The easily accessible processes combined with several automatic data entry possibilities ensure less effort for data capture and management.

Reduction of efforts for data entry:

- Less redundancy due to directly linked datasets (e.g. (S)AE, Medication and Device Deficiencies)
- Direct documentation of ePRO data in the eCRF database
- Direct data transfer from laboratories
- Automatic data transfer from medical devices

Centralized online storage and reporting leads to effective processes:

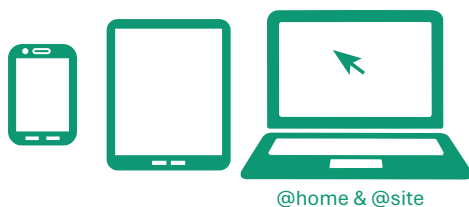
- Risk management based on Study Plan & Relevant Events
- Data management and cleaning
- Risk based monitoring and SDV management
- (Safety) reporting between CROs and Sponsor
- Effective communication with sites

SUPPORTING YOUR PROCESSES

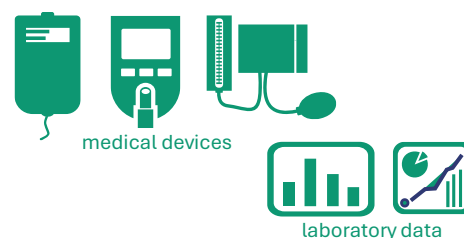
- Integrated plausibility checks
 - Query management
 - Relevant event management
 - Protocol deviation management
- Status overview
- Source Data Verification
- Comprehensible roles and privileges
 - Site recruitment support features
- Data delivery in standard formats
- Ad hoc reports for all purposes

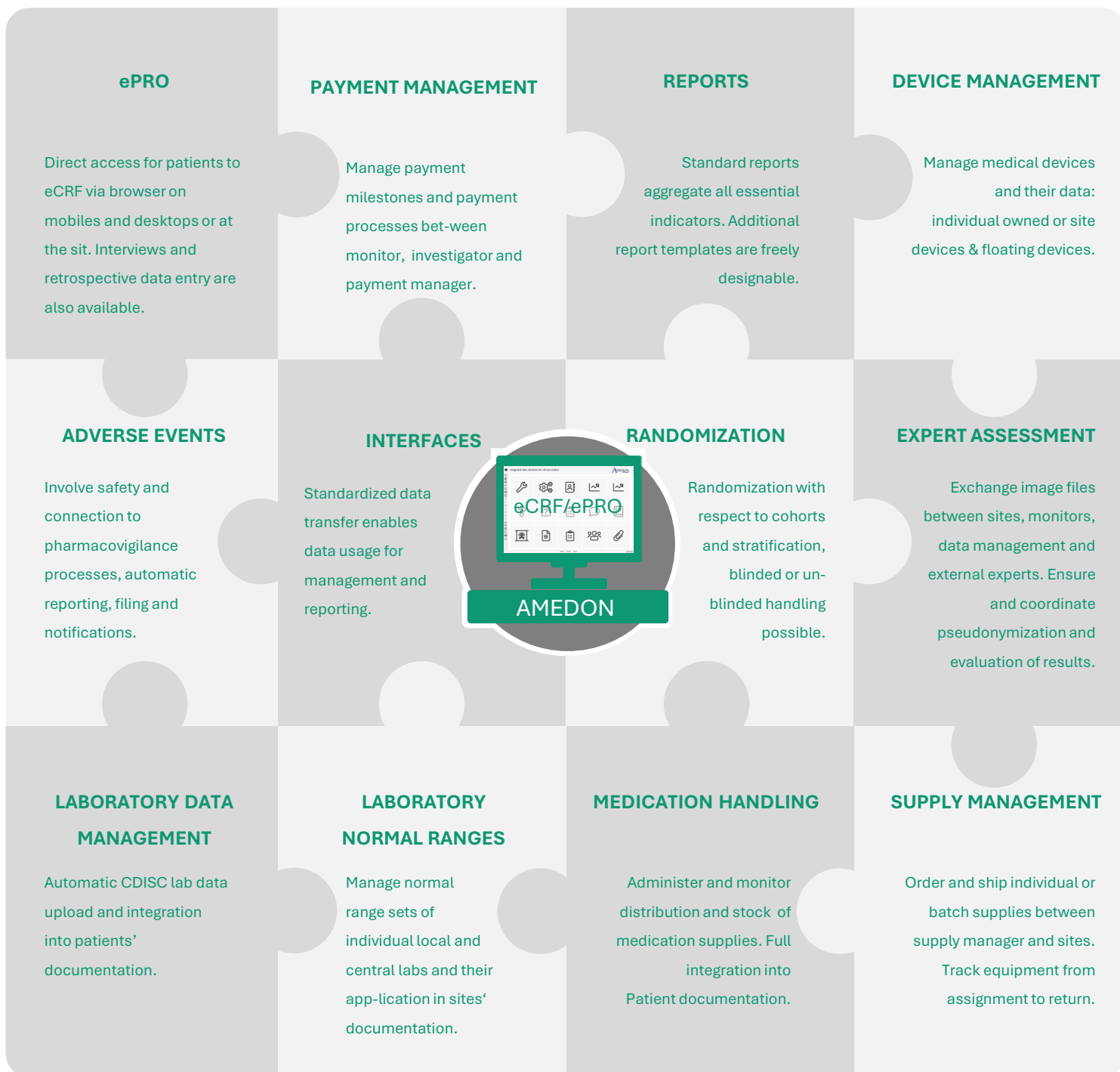
DATA ENTRY POSSIBILITIES

Manual eCRF input devices



Automatic transfer





SECURITY AND STANDARDS

- Data stored in Germany – German Data Protection standards
- Data security: Data center ISO/IEC 27001 certified
- Total Quality Management system

- Validation processes based on GAMP guideline
- Applications prepared to be compliant to FDA 21 CFR part 11
- Study design according to ICH GCP E6

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