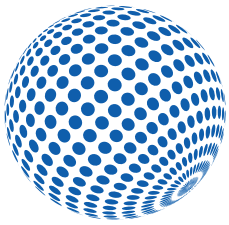


OmniComm®

eClinical Solutions for Life™

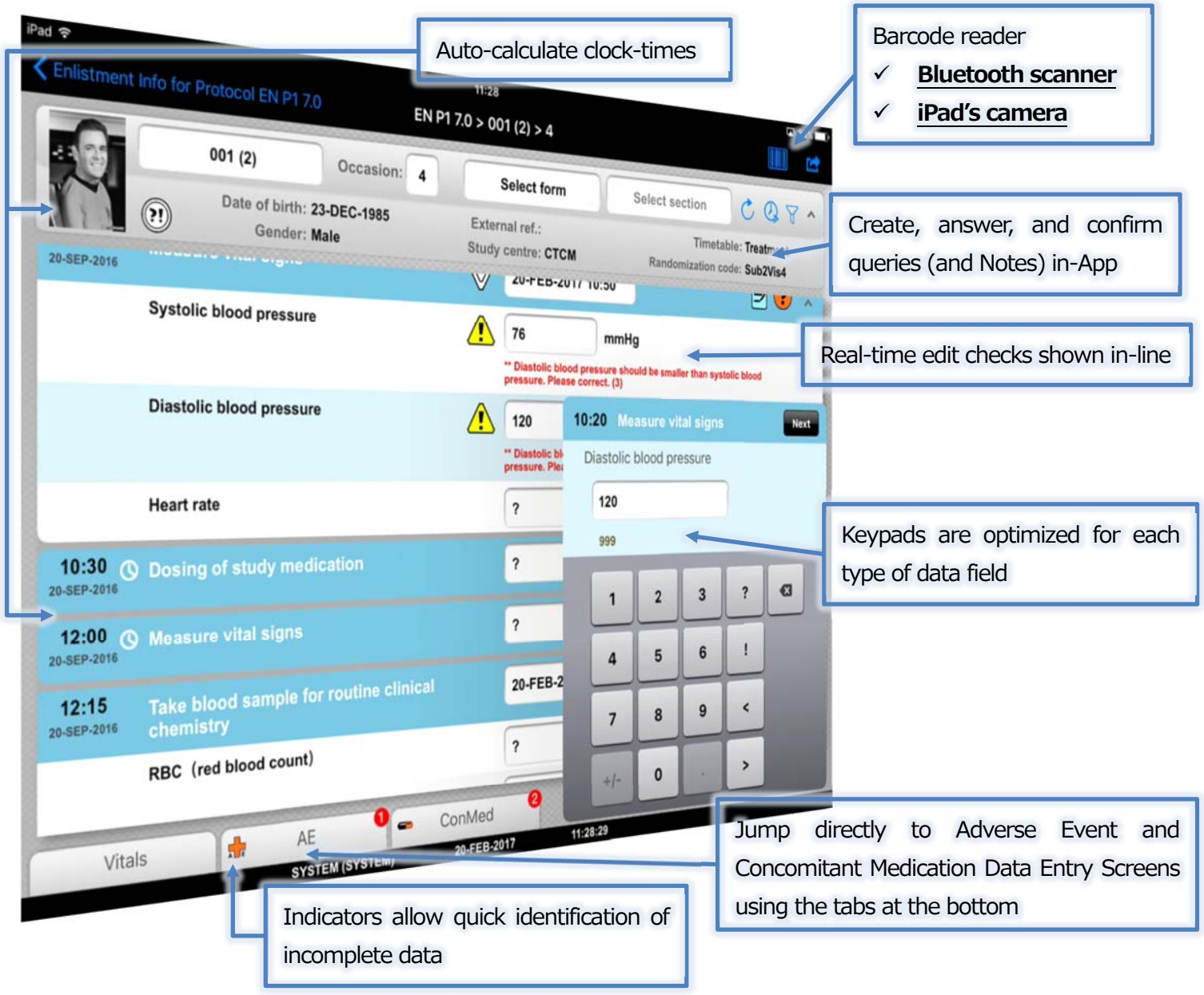
Promasys version 7.3

An integrated clinical trial data management and EDC solution for Investigator Initiated Clinical Trials.

Bedside Data Entry…

Promasys iPad app - Innovative Mobile EDC System

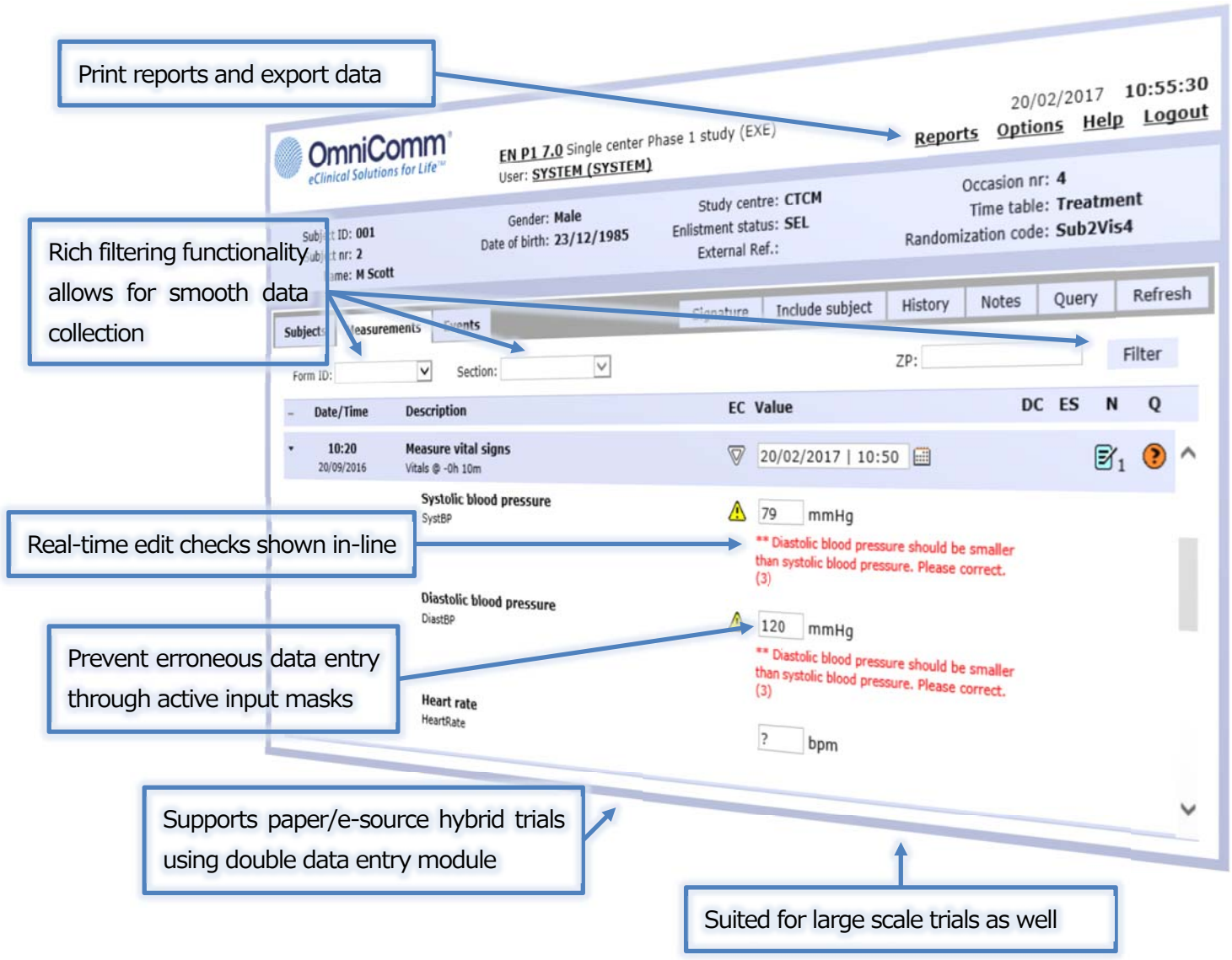
- ☑ Location-free data collection using WIFI or Cellular internet connection
- ☑ Subject registration as well as visit scheduling using the planning module
- ☑ Interface optimized for mobile data collection
- ☑ Jump directly to subject information page or specific data item through barcode scanning
- ☑ Direct image data upload to EDC and viewing/downloading
- ☑ Full electronic signature functionality as well as audit trail viewing available directly from iPad



···as well as Desktop Data Entry

WebCRF - Platform-free Data Entry Interface using standard internet browsers

- ☑ Subject registration and data entry without having to install an application
- ☑ JQuery base: supports all current major browsers
- ☑ Rich CDMS functionality allows for efficient and quality data collection in multi-center research
- ☑ Print CRFs and Data Entry Progress reports, and export datasets directly from browser
- ☑ Direct image and PDF data upload to EDC and viewing/downloading
- ☑ Full electronic signature functionality as well as audit trail viewing available directly from browser



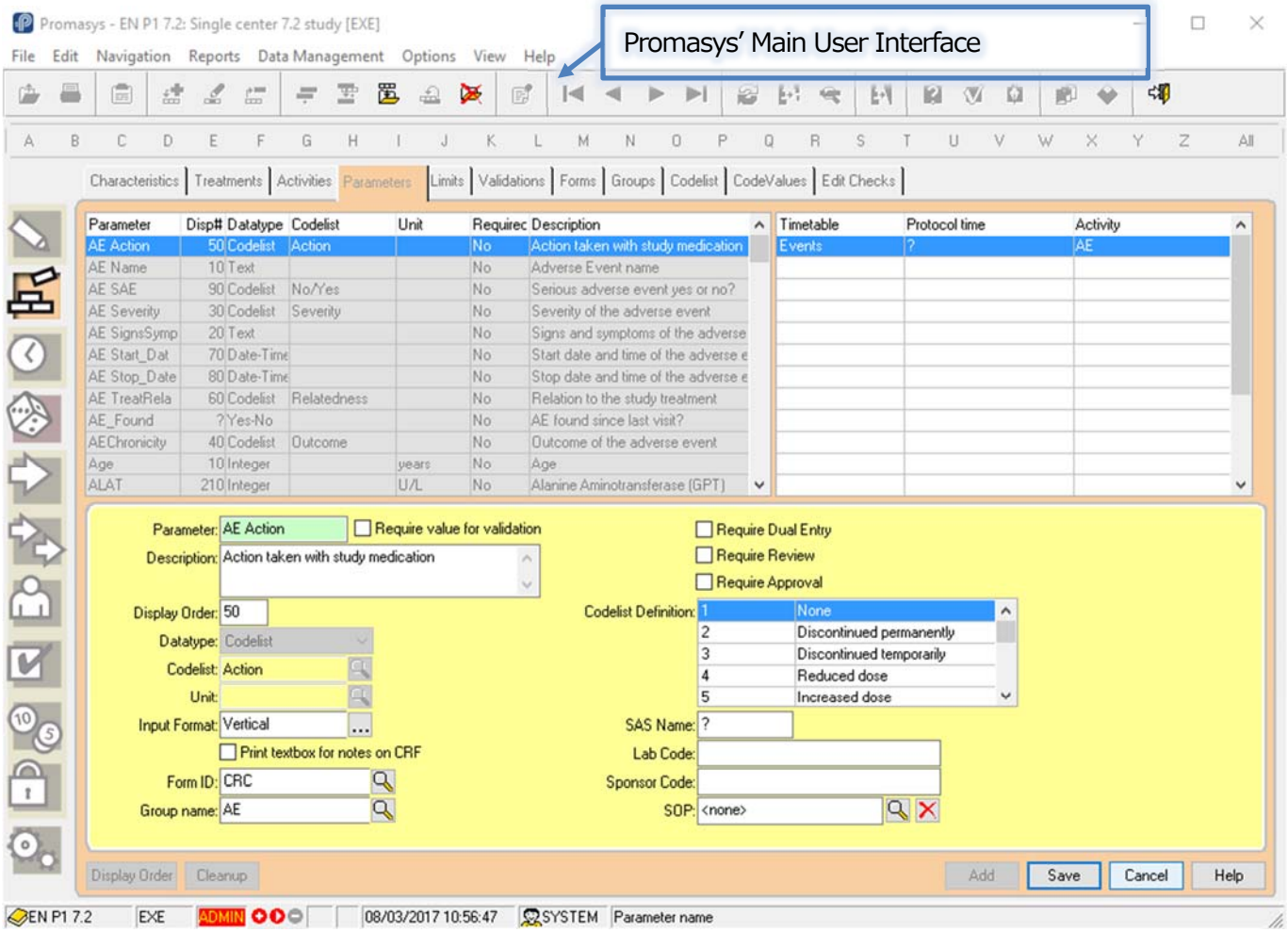
For Academic and Early-Phase Research

The history of Promasys dates back to 1988, when development of the clinical data management system started at the Centre for Human Drug Research in Leiden, the Netherlands. In 2005 Promasys BV was established, with the goal of making Promasys available for researchers and organizations globally. In 2013, Promasys became part of OmniComm Systems Inc., the most innovative EDC solutions provider. As a result, Promasys software is now available anywhere in the world, with 24/7 support throughout the globe.

To date, Promasys software has been used by various types of institutions in Europe, Asia and the USA. Although we count CROs and pharmaceutical companies among our customers, the majority of our clients are academic hospitals, research organizations, and governmental organizations. This reflects the fact that Promasys is particularly well-suited for investigator initiated trials.

No Need for Programming

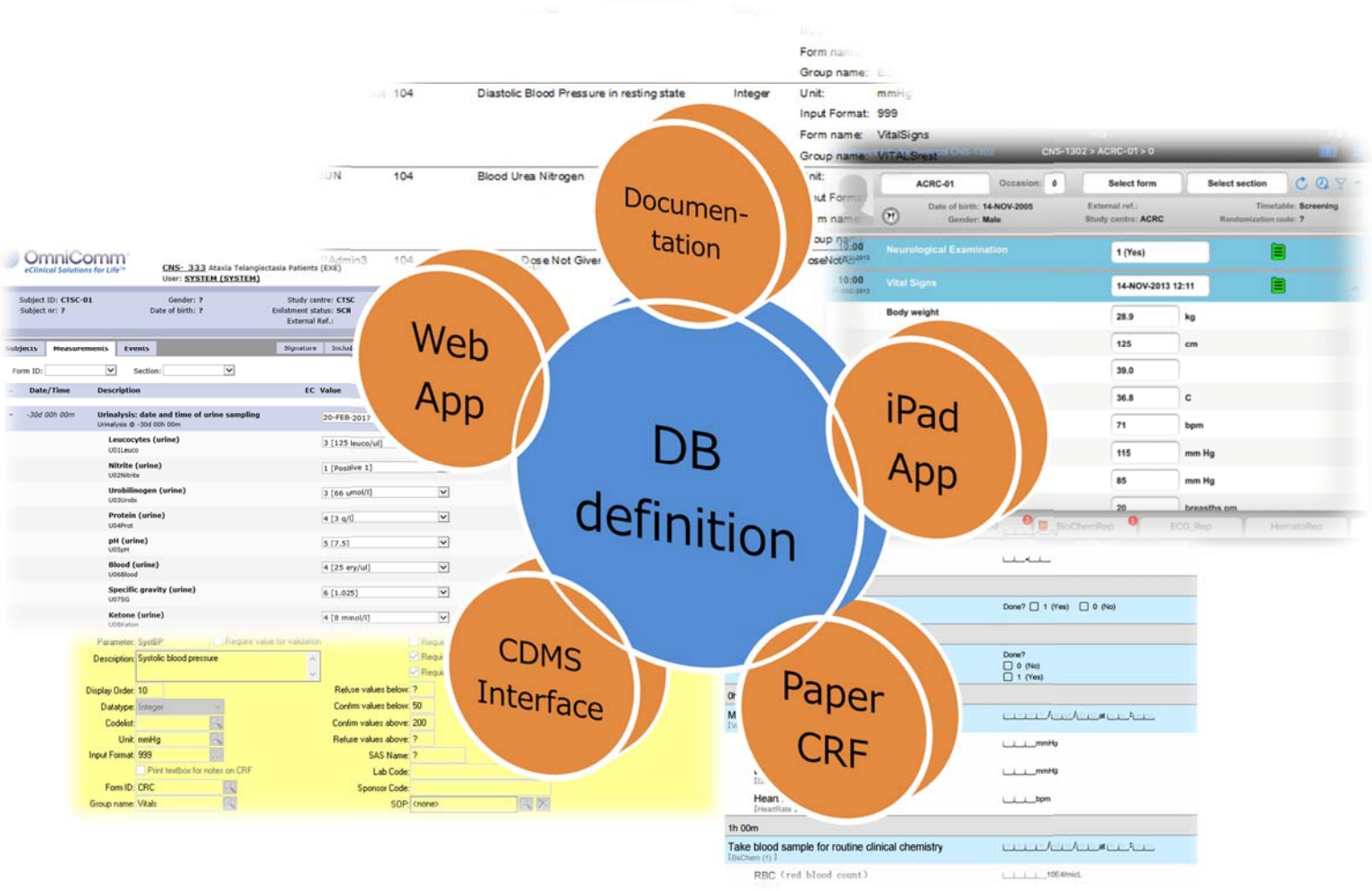
No programming or support from IT specialists is required in implementing and running Promasys. Promasys uses a consistent interface in all available modules. Users will have the ability to efficiently do all their clinical trial and data management tasks after only a short initial training period.



All UIs Generated from One Design

Promasys allows for generation of CRFs from the study design at any point during the study, allowing for easy reviewing during study definition. The design of paper CRFs can be fully customized to the needs of the data center of study site.

Data Entry modules are similarly generated directly from the study design. Mid-study changes have never been easier, as design changes are reflected directly in the printed CRF as well as the various data entry modules.



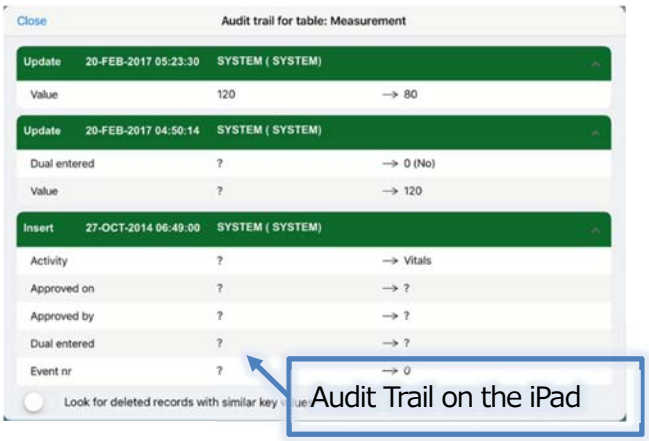
Data entry screens are highly responsive, and allow for stress-free data entry of even large volumes of data. Multiple data entry tools are available, and may be selected depending on the study design or user preference. The rich CDMS functionality allows for filtering of data items in the data entry tools, as well as during printing and data export, providing an efficient user experience in both data collection and data management.

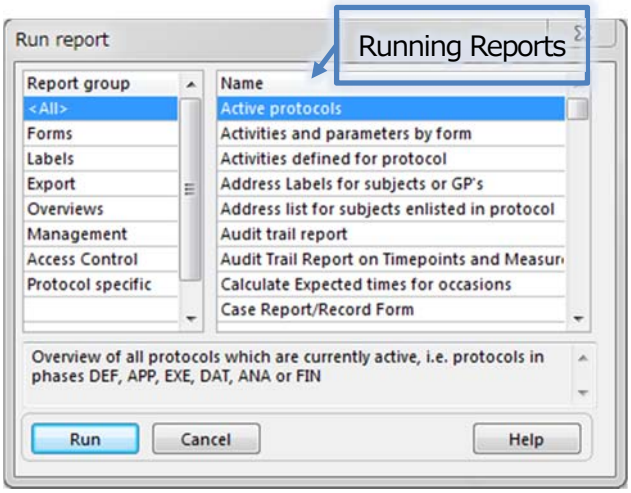
Furthermore, the WebCRF and iPad app interfaces support multiple display languages (which can be fully customized), allowing for site-friendly execution of multinational clinical research.

Print Reports and Export Data

Extensive Library of Reports

Promasys comes standard with an extensive library of more than 70 reports: from subject recruitment progress reports to audit trail listings or data entry progress reports. Reports can be customized using the built-in editor, allowing for parallel use of multiple layouts. Promasys also allows for easy reporting across trials.





Easy Access to Full Audit Trail

All changes in variable values as well as trial design are tracked in the system-generated audit trail. Audit trail information can be viewed from any interface for individual items, a range of items, a specified period, etc... In addition to protecting the integrity of the data, it also serves as a powerful tool in driving efficient quality control, query management, and data cleaning.

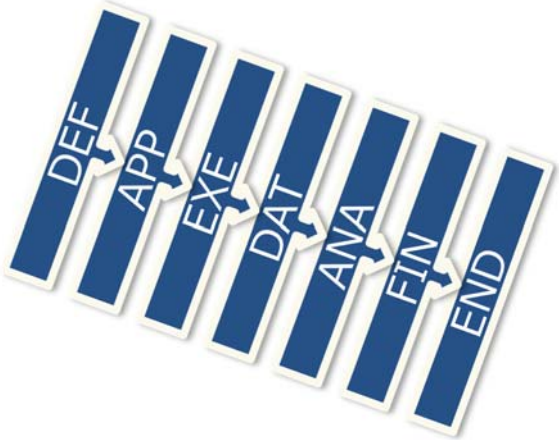
Set-and-Forget Access Control

Fully Configurable Access Control

System access control is managed based on user ID and password. Passwords can be configured to require numbers, special characters, prevent recycling of passwords, and number of failed login attempt before account lockout. For each user or user group, read/write/admin access to protocol, sites, and functionality, as well as rights for queries, reports, signatures can be configured. At the user level, many more configurations, such as method of system access (e.g. iPad only, Web only) and password expiry are available.

Simple Workflow

GCP compliance is supported through the Study Life Cycle™, Promasys' quality engine that divides a clinical trial in 7 distinct phases. Access rights of users are dynamically adjusted when the phase of a trial changes. Quality and integrity of data are guaranteed with minimal user intervention.



Optional Components

Coding Systems

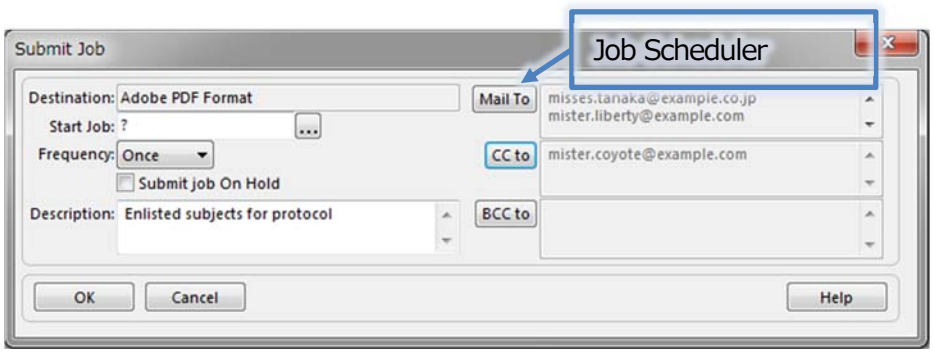
The Promasys Coding Systems option provides a connection to standard coding databases, MedDRA, WHODDD, ATC/DDD and allows the user to perform coding of adverse events and concomitant medication from within the Promasys interface. The Promasys Coding Systems option comes with a tool for importing the coding database files, and allows parallel use of multiple versions.

Import of HL7 messages

Promasys can capture of HL7 messages, allowing for automatic import of e.g. lab data. This makes timely data entry of lab values possible, whilst preventing transcription errors.

Job Scheduler

Reports can be generated in the background and distributed to specified users as email attachment. For instance, a recruitment progress report can be delivered in time for a weekly team meeting.



SDTM Export

OmniComm Systems' flagship EDC, TrialMaster has a powerful mapping tool that can be used by Promasys to export SDTM datasets. The mapping can be done during study definition or execution, allowing for prompt SDTM dataset generation shortly after database lock.

ePRO

Patient Diaries and other patient reported data can be collected directly from the patient's own smart device using Promasys' ePro (Electronic Patient Reported Outcome) capability. Data collected in this way is directly entered into the database.

Promasys will provide researchers/research organizations with tools and services to efficiently conduct quality controlled clinical research and clinical data management without programming and/or support from IT personnel.

PROMASYS

software without side effects

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