

**OmniComm**<sup>®</sup>  
*eClinical Solutions for Life*<sup>™</sup>

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# Promasys version 7.3

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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

The screenshot displays the 'Enlistment Info for Protocol EN P1 7.0' screen. At the top, it shows the subject ID '001 (2)', Occasion '4', and a 'Select form' button. Below this, the subject's date of birth (23-DEC-1985) and gender (Male) are listed. A timeline of events is visible, including '20-SEP-2016 Measure vital signs', '10:30 Dosing of study medication', '12:00 Measure vital signs', and '12:15 Take blood sample for routine clinical chemistry'. The current data entry screen is for 'Systolic blood pressure' (76 mmHg) and 'Diastolic blood pressure' (120 mmHg). A red warning message states: '\*\* Diastolic blood pressure should be smaller than systolic blood pressure. Please correct. (3)'. A keypad is overlaid on the screen, and a 'Next' button is visible. The bottom navigation bar includes 'Vitals', 'AE', 'ConMed', and 'SYSTEM (SYSTEM)'.

Auto-calculate clock-times

Barcode reader  
✓ **Bluetooth scanner**  
✓ **iPad's camera**

Create, answer, and confirm queries (and Notes) in-App

Real-time edit checks shown in-line

Keypads are optimized for each type of data field

Jump directly to Adverse Event and Concomitant Medication Data Entry Screens using the tabs at the bottom

Indicators allow quick identification of incomplete data

# ...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

The screenshot displays the OmniComm WebCRF interface for a study titled "EN P1 7.0 Single center Phase 1 study (EXE)". The user is identified as "SYSTEM (SYSTEM)". The interface includes a header with the OmniComm logo and navigation links for "Reports", "Options", "Help", and "Logout". A subject profile section shows details for Subject ID: 001, Name: M Scott, Gender: Male, Date of birth: 23/12/1985, Study centre: CTCM, Enlistment status: SEL, Occasion nr: 4, Time table: Treatment, and Randomization code: Sub2Vis4. A table of data entries is shown, with a callout highlighting a real-time error check for Diastolic blood pressure (DiastBP) of 120 mmHg, which is flagged as being larger than the Systolic blood pressure (SystBP) of 79 mmHg. The error message reads: "\*\* Diastolic blood pressure should be smaller than systolic blood pressure. Please correct. (3)". Other fields include Heart rate (HeartRate) with a question mark and bpm unit. Callouts from external boxes point to various features: "Print reports and export data" points to the Reports link; "Rich filtering functionality allows for smooth data collection" points to the Subject, Measurements, and Events tabs and the Filter button; "Real-time edit checks shown in-line" points to the error message; "Prevent erroneous data entry through active input masks" points to the input fields; "Supports paper/e-source hybrid trials using double data entry module" points to the interface layout; and "Suited for large scale trials as well" points to the overall interface design.

Print reports and export data

Rich filtering functionality allows for smooth data collection

Real-time edit checks shown in-line

Prevent erroneous data entry through active input masks

Supports paper/e-source hybrid trials using double data entry module

Suited for large scale trials as well

# 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.

Promasys - EN P1 7.2: Single center 7.2 study [EXE]

File Edit Navigation Reports Data Management Options View Help

Promasys' Main User Interface

Parameter	Disp#	Datatype	Codelist	Unit	Requirec	Description	Timetable	Protocol time	Activity
AE Action	50	Codelist	Action		No	Action taken with study medication	Events	?	AE
AE Name	10	Text			No	Adverse Event name			
AE SAE	90	Codelist	No/Yes		No	Serious adverse event yes or no?			
AE Severity	30	Codelist	Severity		No	Severity of the adverse event			
AE SignsSymp	20	Text			No	Signs and symptoms of the adverse			
AE Start_Dat	70	Date-Time			No	Start date and time of the adverse e			
AE Stop_Date	80	Date-Time			No	Stop date and time of the adverse e			
AE TreatRela	60	Codelist	Relatedness		No	Relation to the study treatment			
AE_Found	?/Yes-No				No	AE found since last visit?			
AEChronicity	40	Codelist	Outcome		No	Outcome of the adverse event			
Age	10	Integer		years	No	Age			
ALAT	210	Integer		U/L	No	Alanine Aminotransferase (GPT)			

Parameter: AE Action  Require value for validation

Description: Action taken with study medication

Display Order: 50

Datatype: Codelist

Codelist: Action

Unit:

Input Format: Vertical

Print textbox for notes on CRF

Form ID: CRC

Group name: AE

Require Dual Entry

Require Review

Require Approval

Codelist Definition:

1	None
2	Discontinued permanently
3	Discontinued temporarily
4	Reduced dose
5	Increased dose

SAS Name: ?

Lab Code:

Sponsor Code:

SOP: <none>

Display Order Cleanup Add Save Cancel Help

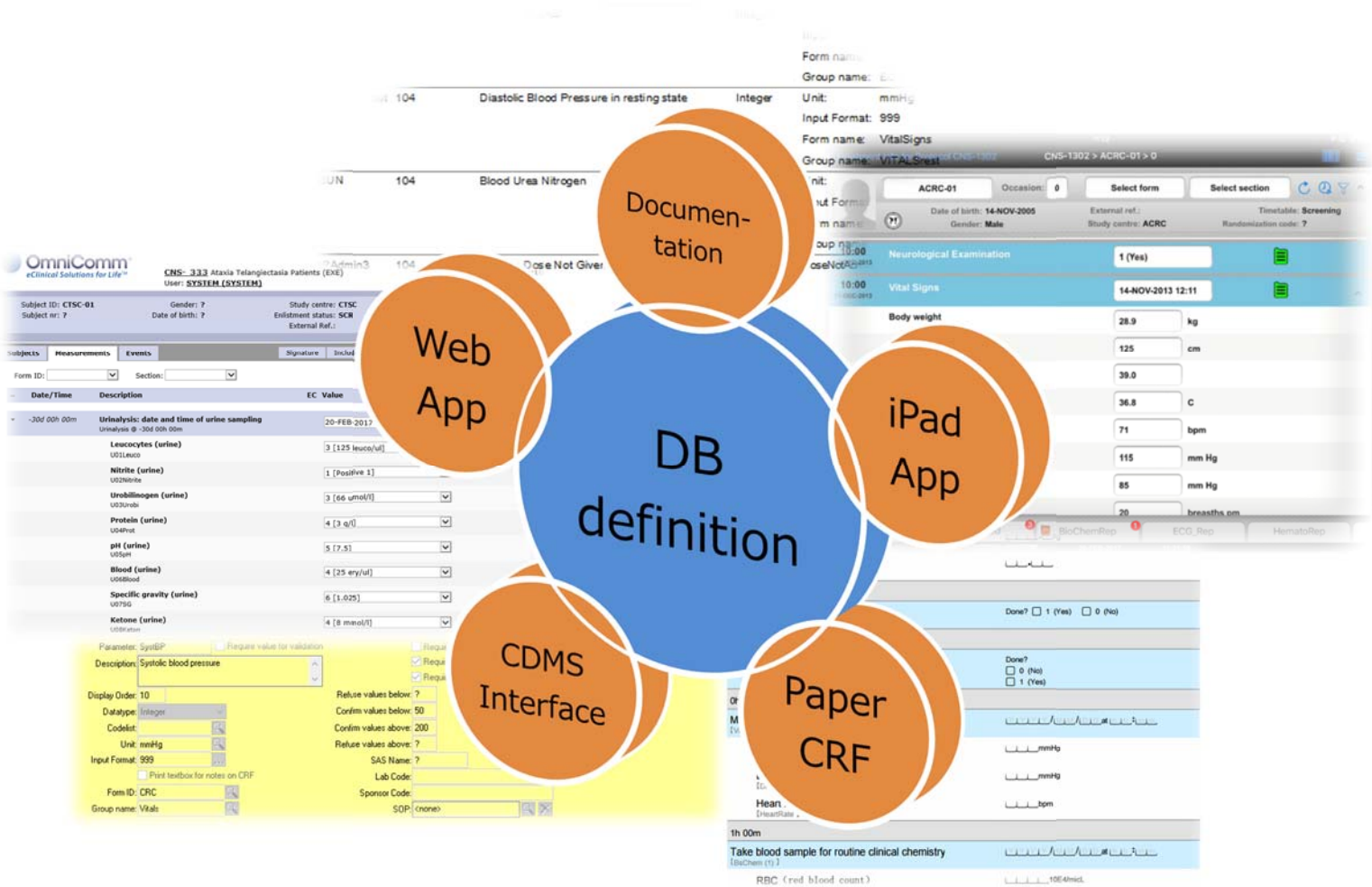
EN P1 7.2 EXE ADMIN 08/03/2017 10:56:47 SYSTEM Parameter name



# 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.

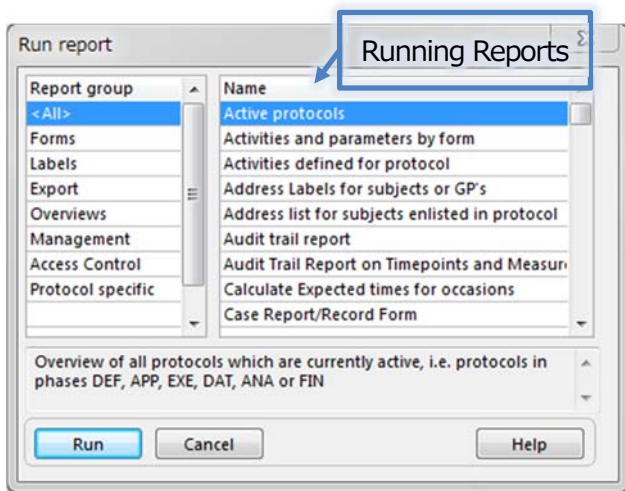
# Print Reports and Export Data

## 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.

Update	Value	Dual entered
20-FEB-2017 05:23:30 SYSTEM ( SYSTEM)	120 → 80	?
20-FEB-2017 04:50:14 SYSTEM ( SYSTEM)	?	?
27-OCT-2014 06:49:00 SYSTEM ( SYSTEM)	?	?

Audit Trail on the iPad



## 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.

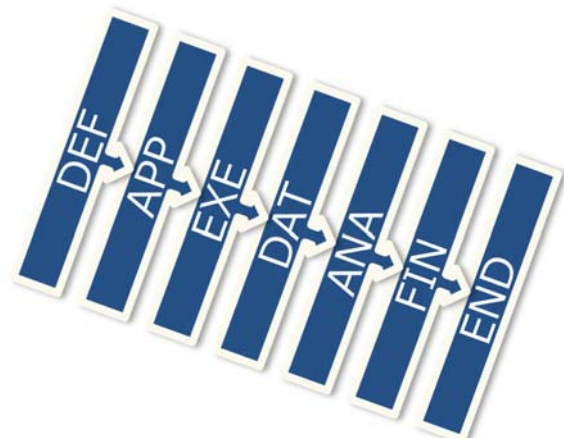
# Set-and-Forget Access Control

## 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

Subject ID: Test456      Event: AE      Seq#: 1

Subject nr: 903

Enlistment status: SEL      Coding System: MDRA\_J171 (v 17.1)

Occasion nr: 1      Preferred Term: 10061165      ガストリン分泌障害

Occasion status: EXE      General Term: 10014698      内分泌障害

Example of Coding using MedDRA-J

## 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.

Submit Job

Destination: Adobe PDF Format

Start Job: ?

Frequency: Once

Submit job On Hold

Description: Enlisted subjects for protocol

Mail To: misses.tanaka@example.co.jp  
mister.liberty@example.com

CC to: mister.coyote@example.com

BCC to:

OK      Cancel      Help

Job Scheduler

## 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.



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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.

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## PROMASYS

**software without side effects**

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