OmniComm®
eClinical Solutions for Life™

TrialMaster® Version 5

Mobile, Multi-Lingual Electronic Data Capture

Introduction

TrialMaster Version 5 is a modern, user-friendly and feature rich system for entering and managing clinical trial data. A culmination of 20 years of product development experience, this latest release features an elegant navigation mechanism, an intuitive user interface, and built-in support for access from desktops, laptops, tablets and smartphones. The release maintains and enhances existing capabilities, including support for any number of foreign languages, extensive data loading capabilities via API calls or file import, flexible reporting, and the industry's only capability to produce SDTM outputs directly from the collected clinical data.

Architecture
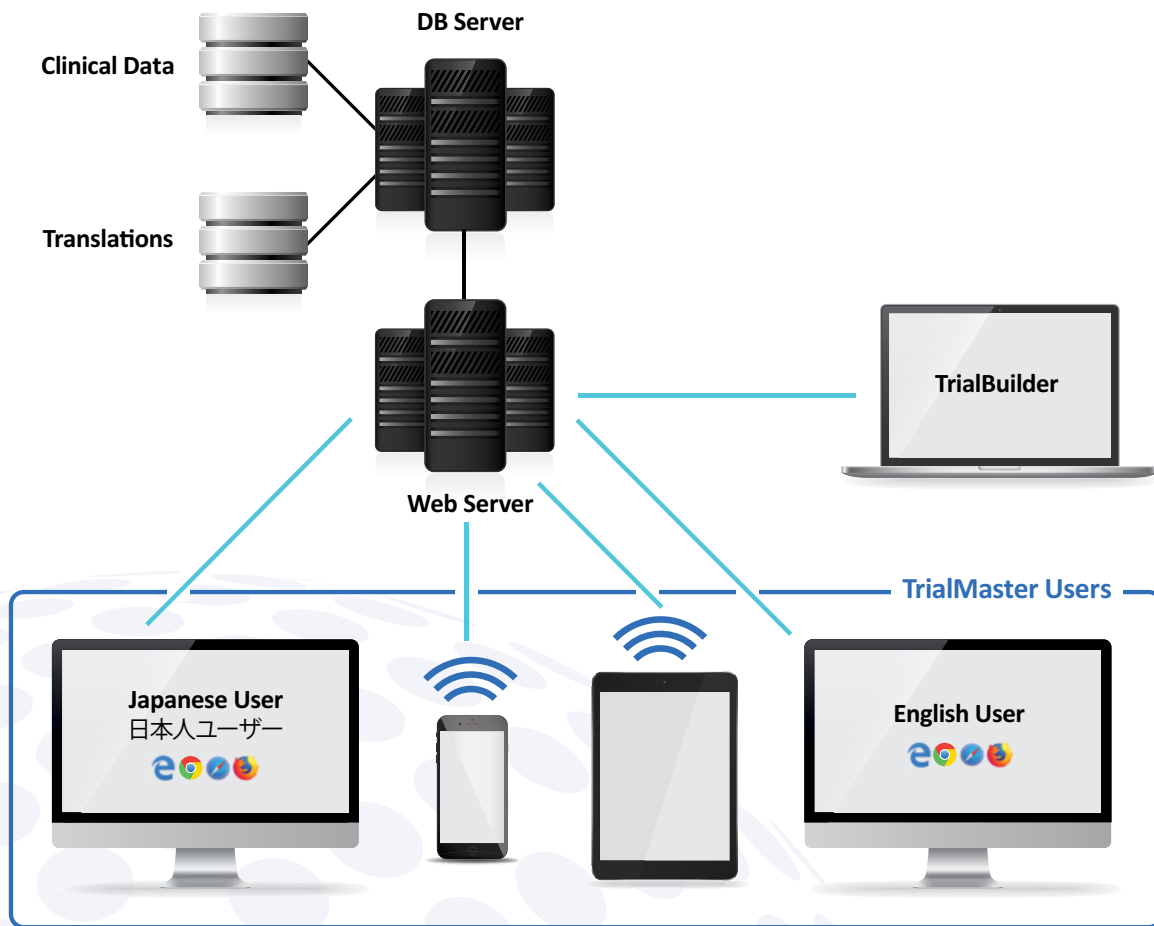
Users connect to TrialMaster using any mainstream browser, and access the corresponding clinical data that is retrieved from the database server. If the trial has been translated into any foreign languages, a user can select his or her desired language and the corresponding foreign language text is retrieved from a global translations database and displayed immediately. In the example above, a Japanese user and an English user could be working simultaneously on the same trial.

A site or sponsor user could also connect to TrialMaster using any commercial tablet, such as an iPad® or a tablet running Android.® TrialMaster is a web application that will respond as any tablet application, for example, to re-orient the display if the tablet is rotated, and to scroll the display on a finger swipe. Finally, patients entering their own data can use any commercial smartphone; TrialMaster will display a stripped-down surround such that the patients can easily enter their data, thereby bypassing the need for a separate ePRO system.

Personnel who are developing trials have access to an elegant, multi-window design tool running under Windows 10.® This tool connects to the central database using a web service connection, giving the dual benefits of local responsiveness coupled with central storage of the trial metadata.

Entering and Managing Data

TrialMaster renders the actual Case Report Forms using a state-of-the-art "liquid layout" technology, whereby the entry fields are displayed according to the form factor and screen size of the user's device. The following diagram shows the same CRF displayed on three different devices:
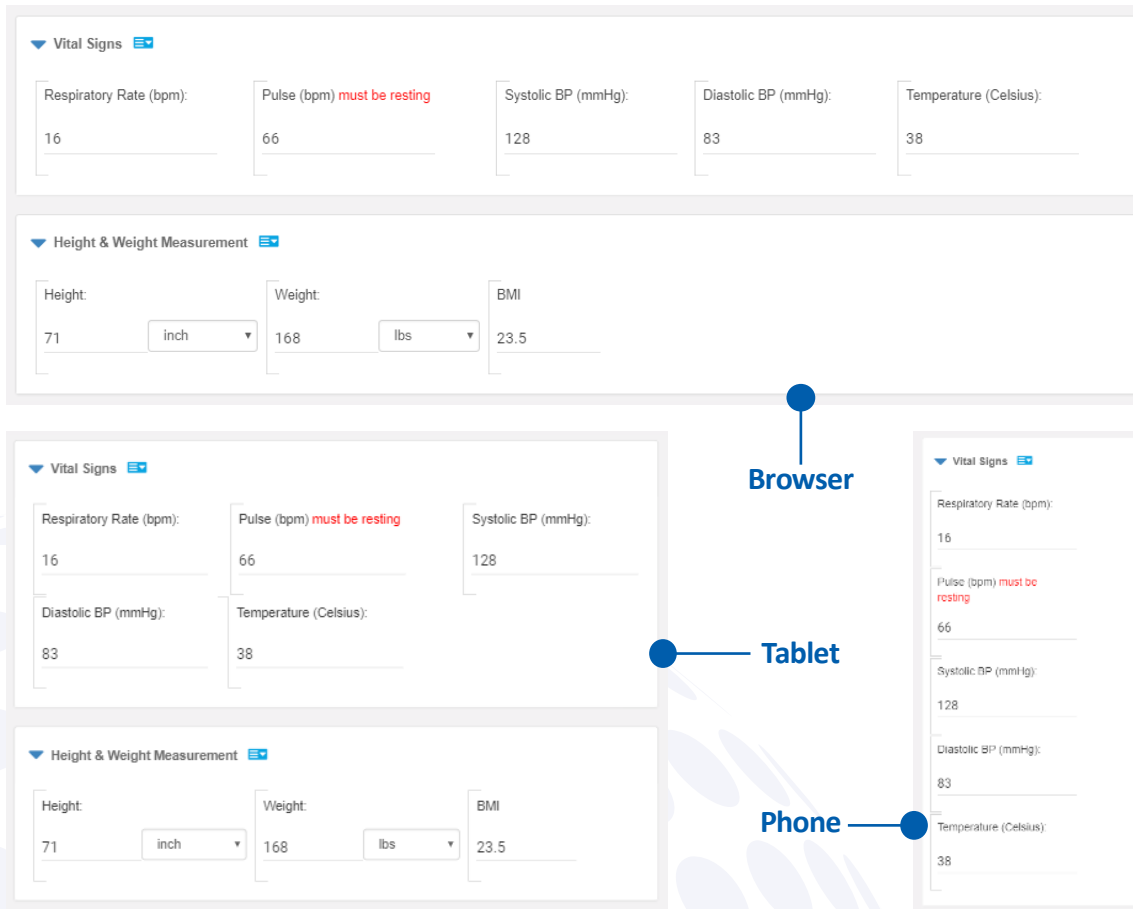

The fields "flow" in real-time, for example, if the browser window is re-sized or the tablet is rotated. Additionally, during data entry, the application responds at the keystroke level. The following example shows the system response as the user completes one of the fields:

Keystroke Responsiveness
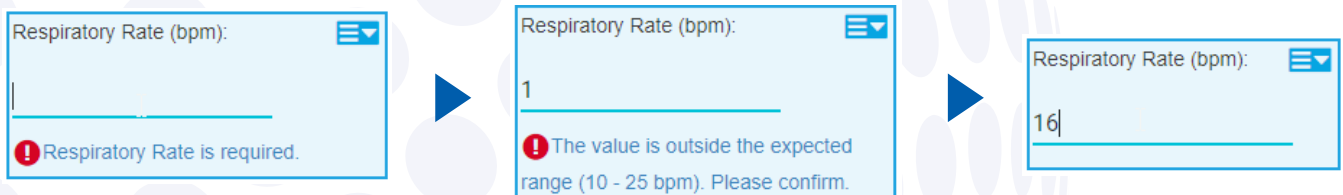
TrialMaster alerts users to any issues immediately, rather than waiting until the form is saved. If the user needs to respond to the edit check, for example, to explain why the respiratory rate is not available, the user would click on the hyperlink "Respiratory Rate is required" and respond to the resultant fly-out dialog. Two clicks and they're on to the next field.

TrialMaster also supports flexible navigation through the forms, supplying more than the traditional sequence of picking a visit and then the forms in that visit. The following diagram depicts the options:
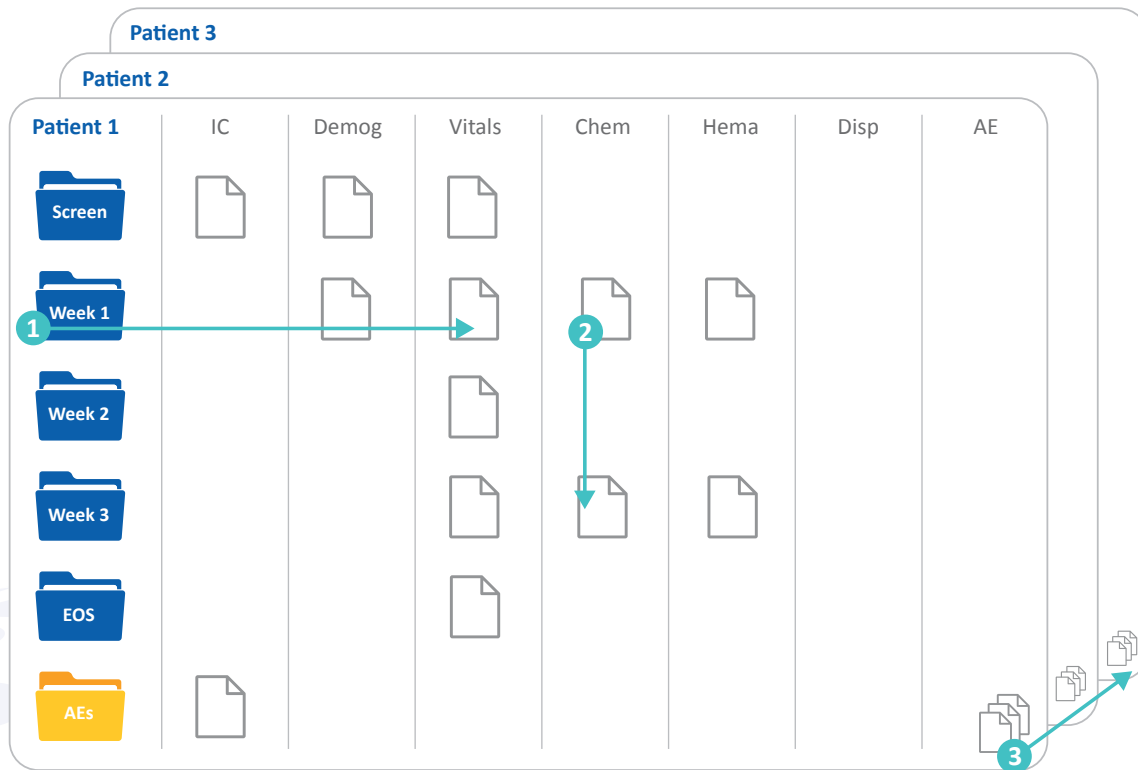
1 = By visit, across forms
2 = By form, across visits
3 = By visit and forms, across patients

Option 1 is the traditional sequence. Option 2 allows the user to select a form and then traverse through all visits where that form exists. Option 3 allows the user to select a visit/form combination and then traverse through a set of patients; this technique could be useful for veterinary studies, where the same data must be recorded quickly for a sequence of animals.

For monitors, the same convenient techniques apply. There are also bulk operations available, including options to bulk-monitor a whole visit, or produce a PDF casebook for a set of patients. Coupled with TrialMaster's dynamic monitoring capabilities to automatically select a subset of data for SDV, these capabilities make optimum use of a monitor's precious time onsite.

Query Management

TrialMaster generates fewer queries than most EDC systems, because edit checks can steer the user to what is expected next. For example, consider the interplay between Ongoing and Stop Date below:

In the first illustration, the event is marked as Ongoing, so the Stop Date item is not enterable (as evidenced by the cursor turning into a No Entry sign). In the second illustration, the event is not Ongoing, so the Stop Date item becomes required and enterable. It is therefore impossible to enter inconsistent data, so no query would ever be generated.

However, for cases where an edit check or manual entry does create a query, TrialMaster has sophisticated capabilities to manage the lifecycle. These include:

• Configurable workflow, by role

• Configurable standard text for query content and query response

• Ability to route a query to individual users

• Ability to hide a query from specific roles

• When a query triggers a data change, the option to use the change reason as the query response

• Bulk operations, for example, to bulk close a set of common queries

• Filterable query reports, with drill-down to the constituent forms

As with the data entry process, query management has been engineered to be quick and intuitive. A query dialog between site and sponsor personnel looks like a chat message:

Reports, Analytics and Dashboards

TrialMaster not only makes it easy to get the data into the system, it also makes it easy to get the data out. Below is a sample AE listing that embodies some deceptively sophisticated logic:

Data Grid for 10 Patients ⓘ   AE ▾

Patient	Form	Age	Sex	AE Term	Start Date	Serious	Trt Emergent	Meds
001	AE: Nausea	35	F	Nausea	2013/01/01	N		
001	AE: Headache	35	F	Headache	2013/09/16	N		Pepto Bismol
001	AE: Broken leg	35	F	Broken leg	2013/09/03	N		Pepto Bismol
001	AE: Irritable bowel	35	F	Irritable bowel	2015/10/14	N	Y	Pepto Bismol

The listing joins the Adverse Events to the Demographics to include the patient's age and sex, then compares the onset date to the patient's first dosing date to determine if the AE was treatment emergent. The final column lists all the concomitant medications the patient was on at the time of onset. This logic is built as part of the study design and is made available at the user's fingertips, for the whole trial, for a site, or for individual patients.

This same extended design capability allows the production of custom SAS datasets, which can include both the clinical data and operational data (such as query response times). The clinical data can also be mapped against any of the SDTM standards to produce submission-ready datasets. These facilities include the population of derived variables such as "study day," unit-of-measure conversion, pivoting of data to create questionnaire and lab domains, and the creation of supplemental datasets.

TrialMaster also supports the development of graphical dashboards using the adhoc query tool LogiXML. These dashboards can be assigned to specific user roles, so different types of users see different information. The assigned dashboards are then displayed on the homepage when the user logs on.

Additional Capabilities

TrialMaster has a rich set of additional capabilities that go beyond what a traditional EDC system would offer. These include the following:

• Sophisticated security, including Single Sign On

• Management and use of lab reference ranges

• Randomization, both built-in and via integration with OmniComm's IRTMaster

• Medical coding via integration with OmniComm's AutoEncoder

• Generation of safety cases in E2B R3 format

• Generation of email alerts and web service calls via edit checks

• Import and export in CDISC ODM format

• Integrated eLearning, so users must take courses and pass assessments before using TrialMaster

• Submission-ready PDFs of patient data, which preserve any attached files

• Risk-based monitoring and data visualization via integration with OmniComm's Acuity

Further Information

For more information, or to request a product demonstration, please contact: **info@sofpromed.com**.