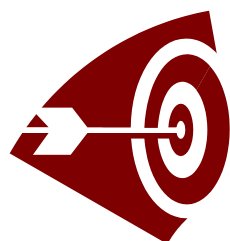




**IRCCS Azienda Ospedaliera Universitaria San Martino – IST**  
**Istituto Nazionale per la Ricerca sul Cancro**  
*Largo Rosanna Benzi, 10 - 16132 Genova - ITALY*



**Clinical Trials Center**

**Remote data-entry Web site**

<http://ctrials.hsanmartino.it/ist/rde/>

**User manual**

Version 2.2

## INDEX

- What you should know before starting 3
- Operating in a while (quick start) 4
- Data-entry tips 5
- About cyclical phases 6
- Frozen forms update 7
- Contacts 9

## WHAT YOU SHOULD KNOW BEFORE STARTING

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The remote data-entry Web site (RDE) of the Clinical Trials Center is designed for gathering clinical data generated within clinical studies.

Data are supplied by the investigators on formatted Web pages called e-Case Report Forms (e-CRFs). These forms are composed of text, fields, check-boxes, radio-buttons and slide menus that supply an efficient and easy way to enter clinical data.

The connection to the Web site is done through a secured protocol (*https*). Investigators collaborating on a clinical study are first given a login and a password (see notes below) by the Clinical Trials Center.

When logged, the investigator must select the clinical study, the patient, and the form to be filled with clinical data. After compilation the form is submitted by the investigator. The Web server checks the data accuracy. If data are out of range, the user is prompted to make necessary corrections to data. When data are correct the Web server stores them in the study database.

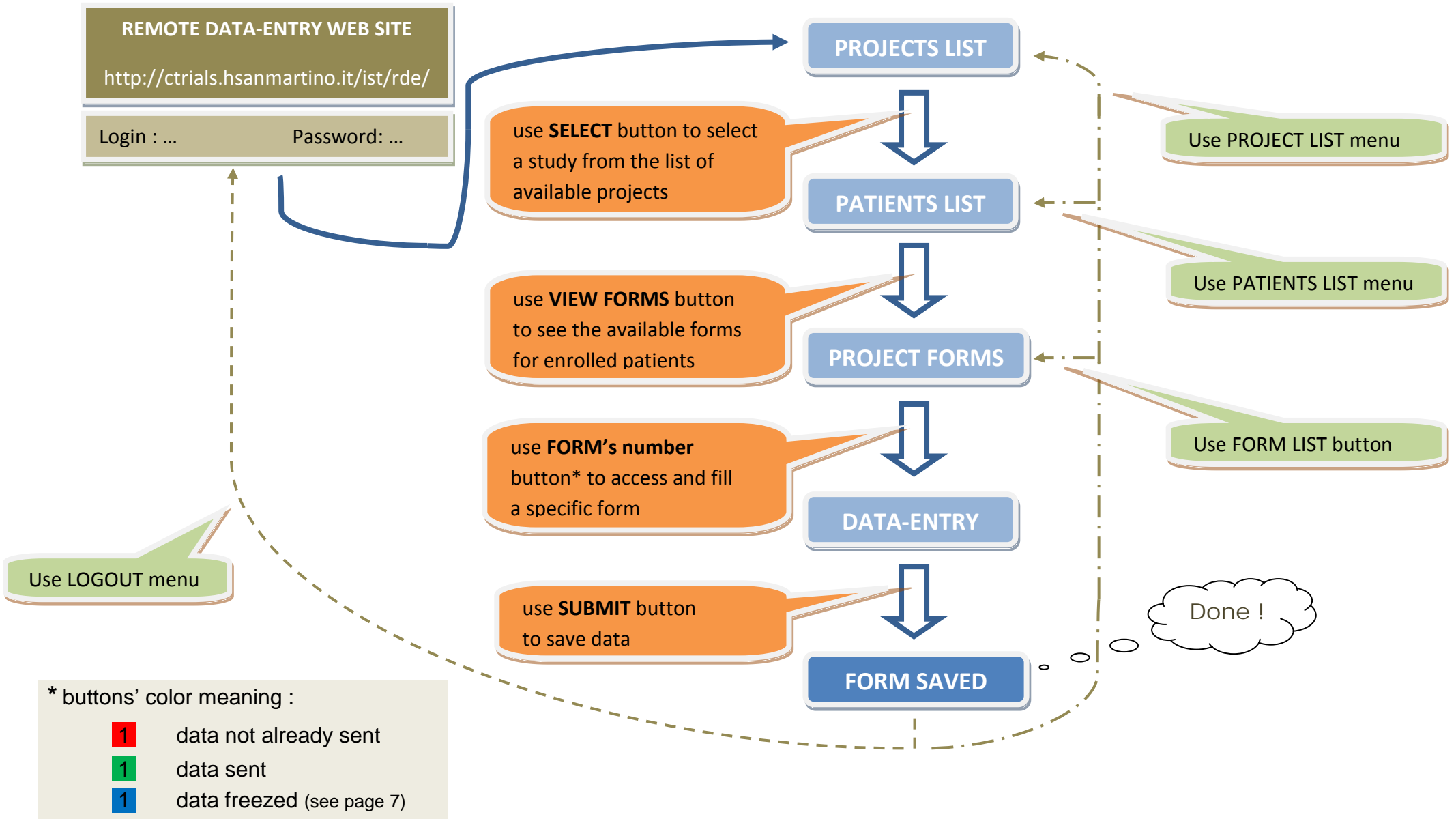
On the next page, you will find a summary of the procedure (quick start).

### Important notes :

- **Investigators' responsibility** : the login and the password supplied by the Clinical Trials Center should be kept **in a safe and secure place** and used **only** by its owner.
- Remote data-entry requires the **Internet Explorer Microsoft browser** (version 8.0 and higher) to have access to the complete forms features. Cookies must be authorized.



# OPERATING IN A WHILE (quick start)



## DATA-ENTRY TIPS

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- About PATIENT INITIALS field

It is a 3 characters field that can be filled in with 3 letters (e.g. MJR) or 2 letters spaced by '-' (e.g. M-C). It is up to the user which combination to use.

- About RADIO-BUTTONS

To cancel the choice, select the radio-button and press *spacebar*.

- About DATES

Dates format is always *dd-MMM-yyyy*, as *10-JAN-2005*.

According to the language set for the clinical study, months could be written :

- in English      *Jan, Feb, Mar, Apr, Jun, Jul, Aug, Sep, Oct, Nov, Dec*
- in Italian      *Gen, Feb, Mar, Apr, Giu, Lug, Ago, Set, Ott, Nov, Dic*

For unknown, dates, type in : **09-SEP-1909** (English) or **09-SET-1909** (Italian)

- About NUMERICAL VALUES

Numerical values can be *integers* (as *15*) or *decimals* (as *15.90*).

For unknown values, type in : **-99**

## ABOUT CYCLICAL PHASES

On the *Project forms* page, forms are grouped by study phases in chronological order. Phases that can be repeated are called cyclical phases. Each new cycle appears when the previous one has been completed.

Cyclical phases have a **New** button available which is activated when a cycle is completed, i.e. all corresponding forms have been filled.

As shown below, the completion of the first and only form for the phase “*Scheda di follow-up*” (follow-up form) activated the **New** button. A click on it made appear a blank form for the next follow-up cycle.

- Users
- Logout
- PROJECT**
- Options
- Countries
- Centres
- Users
- Permissions
- E-mail list
- Documents
- DATA ENTRY**
- Patients list
- Updates
- Data freezing
- Data tracking

Country	Centre	Patient	Patient initials	Date of registration
01	01	1	S-B	19-JAN-2005

**SCHEDA DI IMMISSIONE**

1		1 2
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**SCHEDA DI TRATTAMENTO CHEMIOTERAPICO**

1		1
2		1

**SCHEDA DI VALUTAZIONE DELLA RISPOSTA AL TRATTAMENTO CHEMIOTERAPICO**

1		1
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**SCHEDA DI TRATTAMENTO CHEMIORADIOTERAPICO**

1		1 2 3 4
---	--	---------

**SCHEDA DI INTERRUZIONE DEL TRATTAMENTO**

1		1
---	--	---

**SCHEDA DI FOLLOW-UP**

1		1
2		1

## FROZEN FORMS UPDATE

Data freezing is usually done periodically by the Clinical Trials Center. However, investigators can also freeze forms.

After having frozen a form, investigators might need to modify data. The only way to update a frozen form is to send a request to the Clinical Trials Center data managers, through the **Updates** button near the **View forms** button on the *List of patients* page.

Clicking the **Updates** button will make appear the *Project forms* page relative to updates, each form number being colored in green, red or blue.

**Red** : blank forms (users can fill them on the usual way)

**Green** : filled forms, not frozen yet (users can modify them on the usual way)

**Blue** : frozen forms (users can modify them through the Updates option)

Clicking on a form number colored in blue will make appear the following screen :

The screenshot displays the 'Project forms: send updates' page. At the top, there is a header with 'e-data entry' and user information 'User: Abate A.' and 'Project: GIM7'. A sidebar on the left contains navigation links under 'SYSTEM', 'PROJECT', and 'DATA ENTRY'. The main content area features a table with the following data:

Country	Centre	Patient	Patient initials	Date of randomization	Assigned treatment
01	01	18	T-G	10-FEB-2010	TRASTUZUMAB DOSE RIDOTTA

Below the table, there is a 'BASELINE VISIT FORM' section containing a form number '1' and a blue button with the number '8'. An 'UPDATE' section follows, with a text area for entering new data. At the bottom of the page, there are 'View forms' and 'Submit' buttons.

Fill the *Update* field with the modifications to make on the form. Give **clear and complete explanations** along with eventual justification(s) of the change.

Then click the **Submit** button to send the update request. The Clinical Trials Center will proceed the request as soon as possible and will archive it.

Simply load the corresponding form to check if the work was done.



## CONTACTS

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IRCCS Azienda ospedaliera universitaria San Martino - IST  
National Cancer Research Institute



### **Clinical Trials Center**

Largo Rosanna Benzi, 10  
16132 Genoa  
ITALY

[www.hsanmartino.it](http://www.hsanmartino.it)

Send us an e-mail at : [clinicaltrials@hsanmartino.it](mailto:clinicaltrials@hsanmartino.it) or call

-> for administrative requests : + 39 010 555 84 77

-> for technical questions and troubleshooting : + 39 010 555 84 71

Fax : + 39 010 35 41 03