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 registration/randomization Web site

http://ctrials.hsanmartino.it/ist/rnd/

User manual

Version 2.2

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WHAT YOU SHOULD KNOW BEFORE STARTING

The remote registration/randomization Web site (RND) of the Clinical Trials Center is designed to check patients' compliance with the inclusion/exclusion criteria of a clinical study through a set of questions defined in the research protocol. In case of compliance, the patient is given a unique chronological identification number (registration) and if needed, a treatment arm (randomization).

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.

On next pages, you will find a summary of the procedure (quick start) and some advices on how to proceed to fill a registration/randomization form.

Important notes :

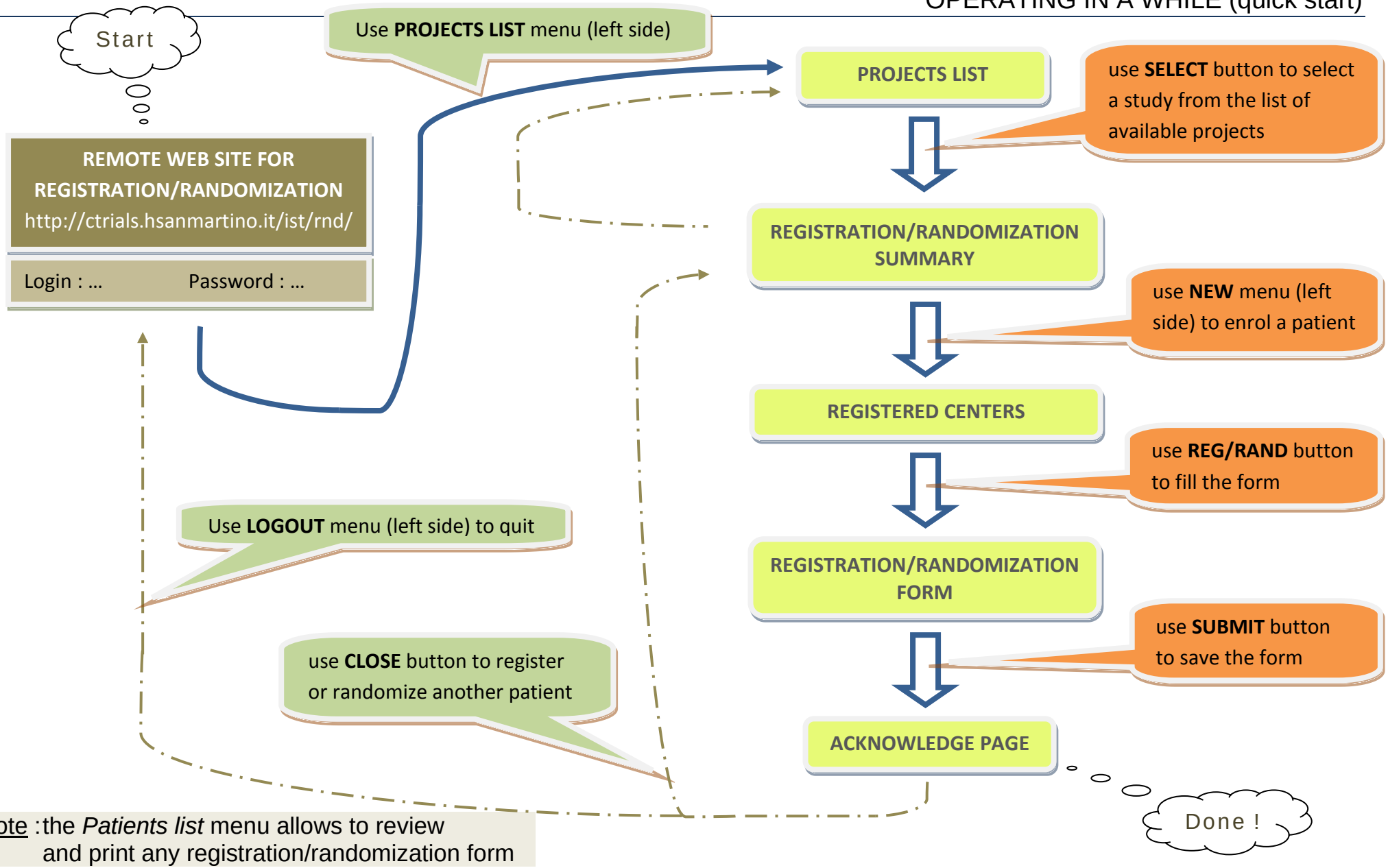
- **Investigators' responsibility :** the login and the password supplied by the Clinical Trials Center should be kept **in a safe and secure place** and used **only** by its owner.

- The registration/randomization of a patient is a "formal" act; supplied data should be **true** and **verified**.

- Once submitted, data can't be modified anymore. After registration or randomization, no patient can be excluded from the study or from the final analysis.

- Remote registration/randomization 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)



Note :the *Patients list* menu allows to review and print any registration/randomization form

ABOUT THE REGISTRATION/RANDOMIZATION FORM

Usually, a registration/randomization form is made of questions about patient's ability to fulfill or not the criteria required to be enrolled in the clinical study.

After getting logged, the investigator simply selects a clinical study, click on the New button to insert a patient, select the corresponding registered center, and fill the registration/randomization form. A simple click is often enough to answer most of the questions (e.g. *Yes*/*No).* Some dates or values (see below) may also be required to the investigators.

When clicking the Submit button the Web server checks the data accuracy. If data is out of range or incomplete, the user is prompted to make the necessary corrections. When data are correct, the Web server stores them and a acknowledge page is displayed.

- 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.*

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

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*

- About NUMERICAL VALUES

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

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

CONTACTS

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

Clinical Trials Center

Largo Rosanna Benzi, 10
16132 Genoa
ITALY

www.hsanmartino.it

Send us an e-mail at : 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