

eTRIALS®

User's Guide | Investigator

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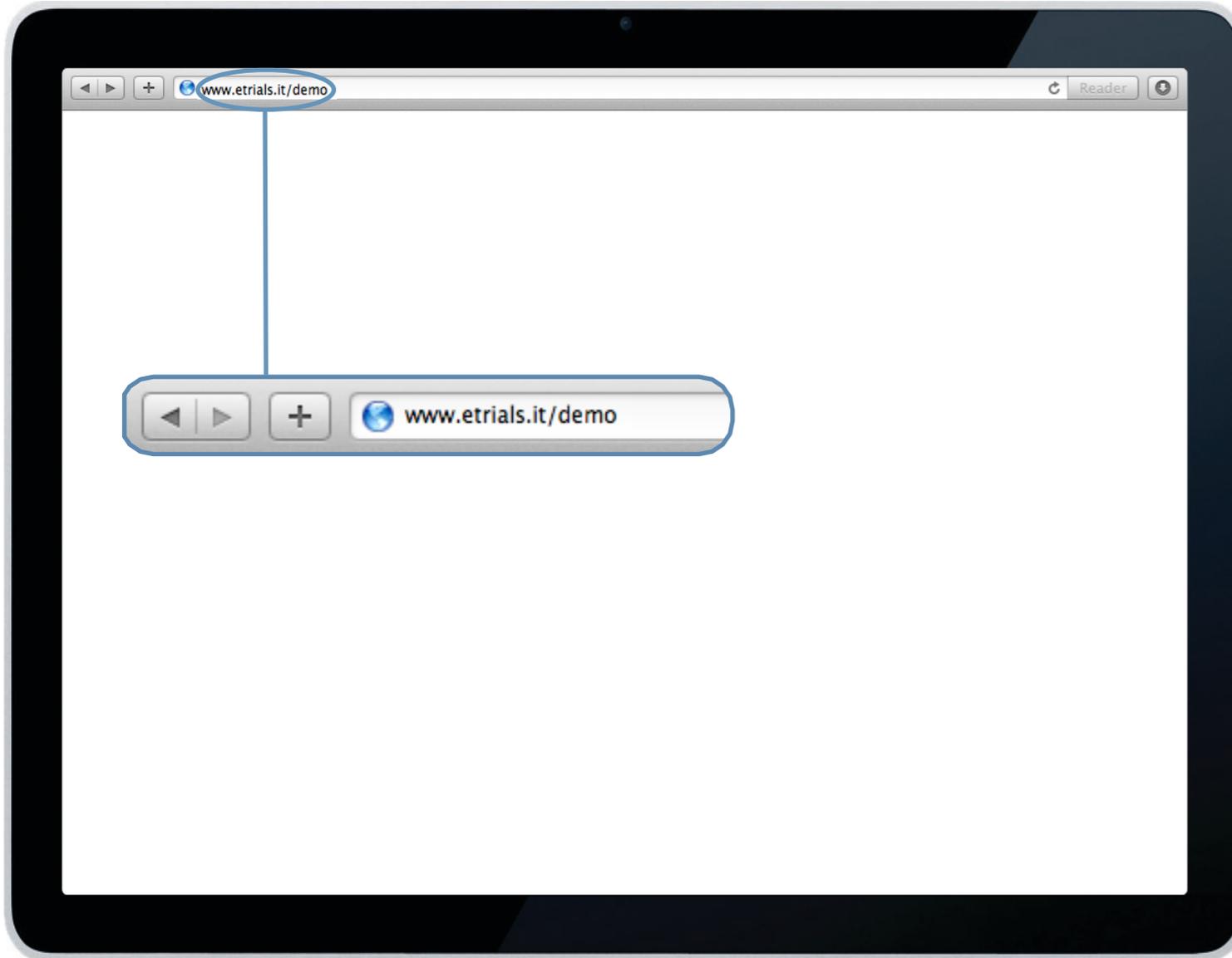
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CHAPTER 1

LOG IN



1.1 How to access the system

Start the Web browser installed on your computer (e.g. Internet Explorer, Firefox, Safari, Opera, Chrome) and type on the address bar the URL address of the eTrials® platform to which you would like to access:

www.etrials.it/name_user

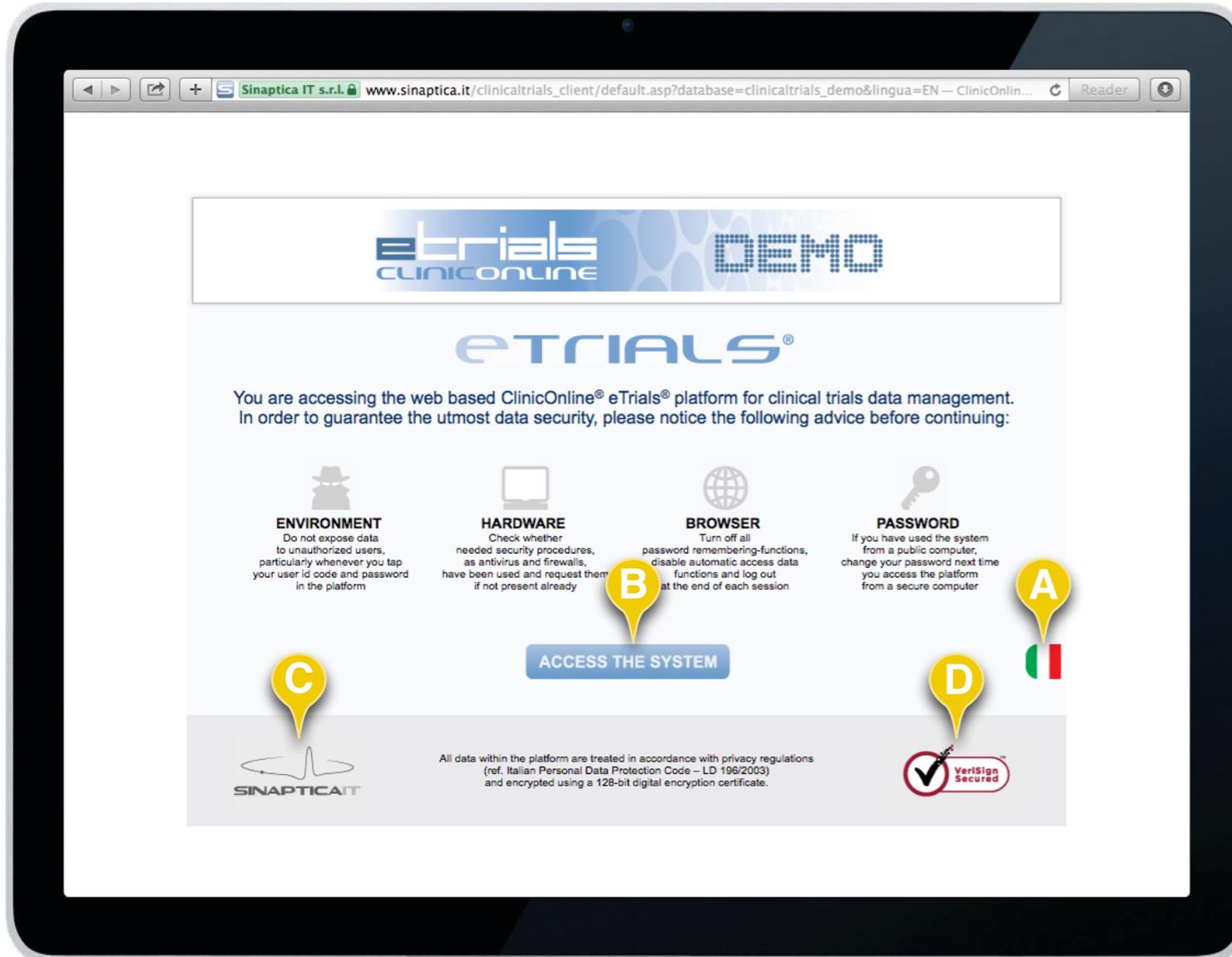
We have used a demo environment for this tutorial setting.

END OF SUBJECT ■

 In case you log into the system using a public Internet point provider or a shared computer, we advise you to make sure that nobody can actually see your user id and password while you fill them in and to clear your browser's cache when you end the session. We also advise you to change your password next time you access the system from your own computer. We recommend the App Webcom® for maximum security without inserting code and password, but using their smartphones.

 In order to speed up the Log In procedure you can add the eTrials® website address to your browser's bookmarks. We also advise you to add the eTrials® bookmark to the Favorites Toolbar.

INVESTIGATOR'S USER GUIDE



1.2 How to select your language

The system access pane reminds Users of the behavioral approach that allows them to enhance the inner security characteristics of eTrials®. The system automatically identifies the browser language and proposes one of the available ones. You can change the language by selecting the appropriate icon (A).

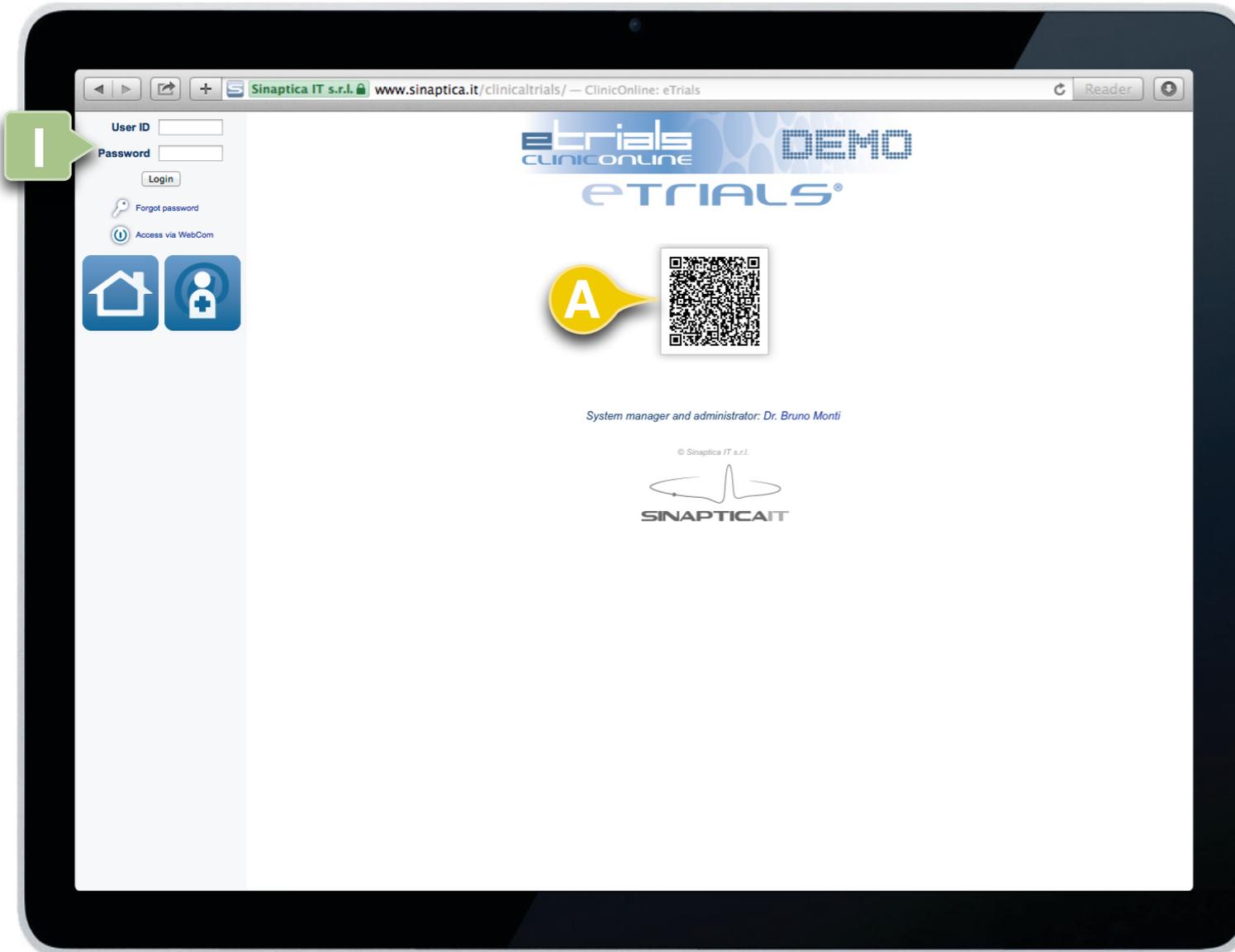
To access the system select the *Access the System* function button (B).

The system also displays two different links: one to the www.sinaptica.it website (C) and a second one to the 128 bit VeriSign Digital Certificate (D).

END OF SUBJECT ■

 The eTrials® web platform has been designed to offer the maximum data transfer security. Indeed, the HTTPS security protocol is active since the first window.

INVESTIGATOR'S USER GUIDE



1.3 Log In

eTrials® automatically proposes two different ways of logging in:

- The first, using the QR-Code (**A**), which can be read using the WebCom® App from your smartphone. After having set up your own User information in the App, you can access the platform without needing to use your User ID and Password.
- The second, (**I**) consisting of the classical log in modality providing your User ID and Password and selecting the Login function key to access the system.

Select Access via WebCom to see the QR-Code login steps.

END OF SUBJECT ■

 Most recent web browsers ask users whether they want to save their User id and password. This is an option that we strongly encourage you not to choose as it makes these two elements –whose secrecy is essential to guarantee data security and users' privacy–, potentially available to third parties

 If you have forgotten your password just click on the following hypertext link to ask for a new one: 'I forgot my password!' and follow instructions.

CHAPTER 2

HOMEPAGE

INVESTIGATOR'S USER GUIDE

The screenshot shows the eTrials® Investigator's User Guide homepage. The interface is divided into two main areas: a navigation area on the left (I) and a working area on the right (II). The navigation area includes a user profile for Dr. Mario Rossi, a home button, a user icon, a Template button, a CRF button, and a sidebar with buttons for CLINICAL TRIALS, QUERY, FORUM, and ADDRESS BOOK. The working area displays a welcome message for Dr. Mario Rossi, a date and time indicator, and three sections for clinical trials: DEMO Phase I, DEMO LAL, and DEMO Oss. Each section shows statistics for Groups, Patients, CRF, and Query, along with a 'Planner' button and a 'New Patient Registration' button. A '1 new query' notification is visible at the bottom left.

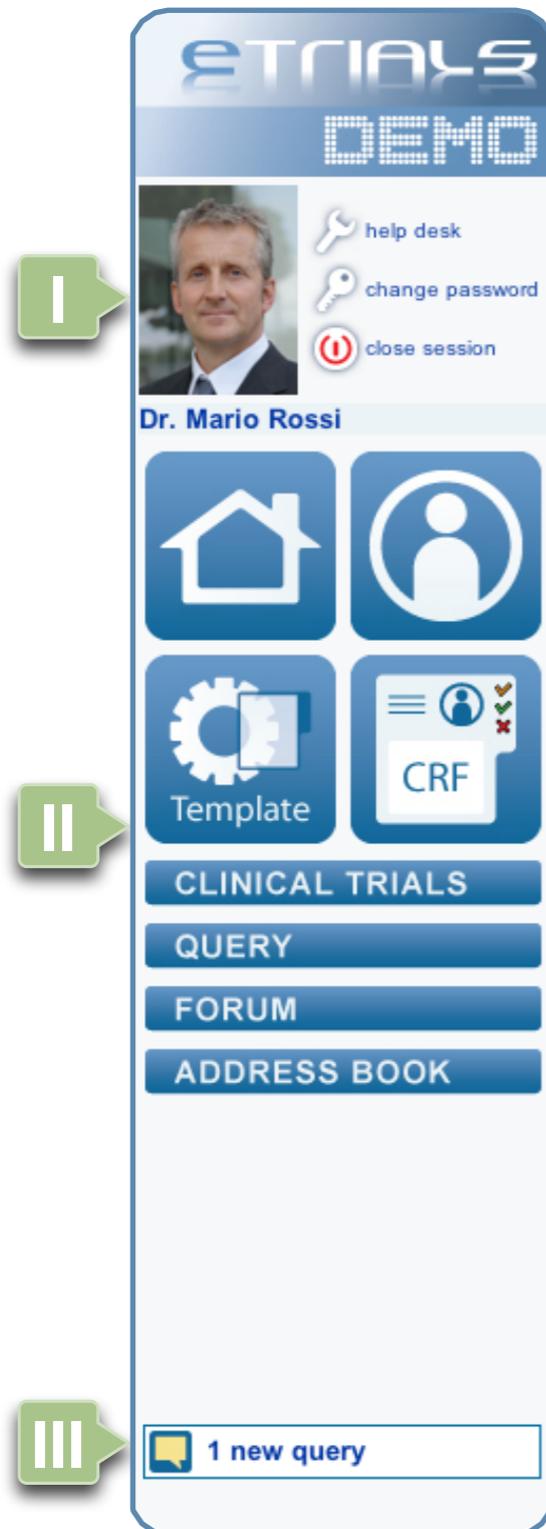
2.1 Structure and functioning

Once you have logged in, the system displays the eTrials® Homepage, in which workspace is divided into two different areas.

On the left, the navigation area with keys and buttons that allow you to access the different functions of the system (I).

On the right, the working area (II).

[CONTINUES ►](#)



In the navigation area there are three different sections:

I User's Area. It displays the logged in operator information and eTrials® operator's management functions: by clicking on his/her name or on the image you will access to his/her personal data.

II Menu Area. Where you will find buttons and keys to activate eTrials® functions:

- Home.
- Patients.
- CRF Templates.
- CRF.
- Clinical Trials.
- Query.
- Forum.
- Address book.

III Messages Area. Where you will find queries notices.

[CONTINUES ►](#)

The screenshot displays three clinical trial panels, each with a 'Planner' button and a 'New Patient Registration' button. Callouts A through H highlight specific features:

- A:** Clinical Trials online: 3
- B:** Clinical trial code and description (e.g., DEMO Phase I - eTrials DEMO Phase I)
- C:** New Patient Registration button
- D:** Planner button
- E:** Clinical trial Groups (e.g., Bologna: 5 pat, 16 crf; Roma: 2 pat, 7 crf)
- F:** Clinical trial Patients (e.g., 33833138: 3 crf; 38507820: 4 crf; 45271279: 4 crf; 49576546: 1 crf; 65171639: 4 crf)
- G:** Patient's active CRF forms (e.g., not yet closed: 0; closed and signed: 7; validated: 16; rejected: 0)
- H:** Clinical trial Queries (e.g., to read: 0; to answer: 1; answered: 1)

The second panel (DEMO LAL - eTrials DEMO Studio LAL) shows:

- E:** Clinical trial Groups (Bologna: 1 pat, 1 crf)
- F:** Clinical trial Patients (74407021: 1 crf; 93067299: 0 crf; 96915261: 0 crf)
- G:** Patient's active CRF forms (not yet closed: 1; closed and signed: 0; validated: 0; rejected: 0)
- H:** Clinical trial Queries (Query: 0)

The third panel (DEMO Studio Operazionale) shows:

- E:** Clinical trial Groups (Bologna: 4 pat, 10 crf; Roma: 4 pat, 21 crf)
- F:** Clinical trial Patients (11206795: 1 crf; 12624031: 5 crf; 23143441: 1 crf; 29711892: 18 crf; 61095711: 1 crf)
- G:** Patient's active CRF forms (not yet closed: 17; closed and signed: 9; validated: 0; rejected: 5)
- H:** Clinical trial Queries (to read: 0; to answer: 1; answered: 2)

In the working area, you will find the info pane that summarizes the main activities of the logged in operator.

Clinical Trials online (A) shows you the number of clinical trials to which the operator has been associated. For each authorized study, the following information is listed:

- Clinical trial code and description (B).
- Function button to register a new patient (C).
- A key to access the Planner of the related clinical trial (D).
- Clinical trial Groups to which the operator has been associated (E).
- Clinical trial patients with which the operator is authorized to work (F).
- Patient's active CRF forms with which the operator is authorized to work (G).
- Clinical trial queries sent to addressees that have been associated to the same group the operator has (H).

Furthermore, for each Group, Patient and CRF you will find the number of active CRFs, which means, the forms the operator is actually authorized to work with:

- The Group list reports the number of patients and active CRFs per Group.
- The Patients list reports the number of active CRFs per Patient.
- The CRFs list shows the total number of active CRFs, listed according to their approval status (not yet closed, closed and signed, validated, rejected).

In what Queries concern, it is also stated the number of Queries related to the groups pertaining to the operator, listed according to their status (to read, to answer, to solve, solved).

i By selecting any of the fields in the Groups, Patients or CRF lists, the system immediately shows you the corresponding active case report forms (CRF). This solution prevents from having to go through the Search tool of the CRF function or through the Patients tool to search for active forms.

By selecting any of the fields in the Query list and without going through any other search engine the system immediately displays Operator related Queries.

END OF SUBJECT ■

INVESTIGATOR'S USER GUIDE

The screenshot shows the eTrials® Investigator's User Guide homepage. The interface is divided into a sidebar and a main content area. The sidebar on the left contains the user's profile (Dr. Mario Rossi) and navigation buttons for Home, Profile, Template, CRF, Clinical Trials, Query, Forum, and Address Book. The main content area displays three study cards, each with a 'Views' button. A yellow callout bubble labeled 'A' points to the 'Views' button in the first study card, 'DEMO Phase I - eTrials DEMO Phase I'.

Study Name	Groups	Patients	CRF	Query
DEMO Phase I - eTrials DEMO Phase I	2	8	25	3
DEMO LAL - eTrials DEMO Studio LAL	1	3	1	0
DEMO Oss - eTrials DEMO Studio Osservazionale	2	8	31	3

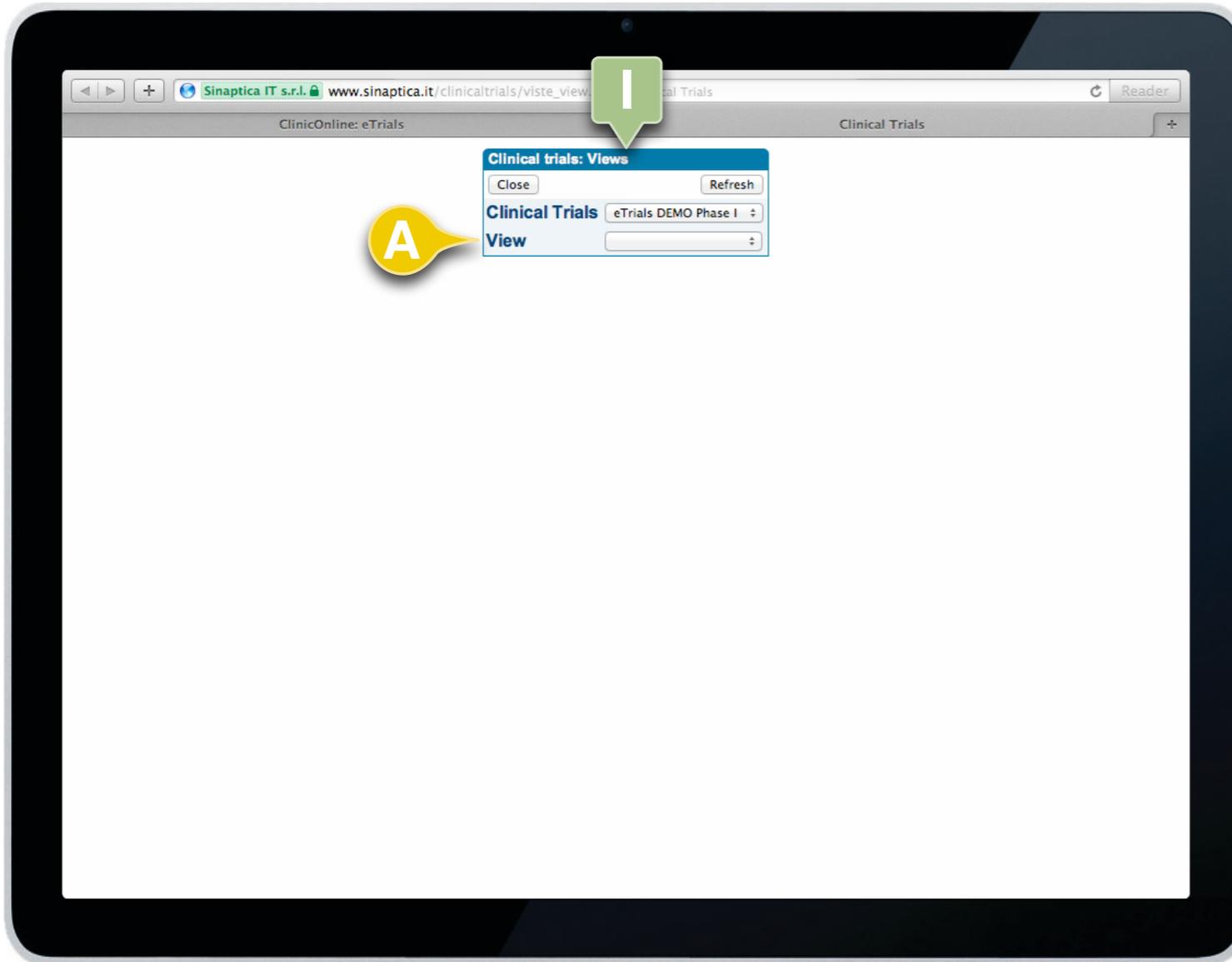
2.2 Views

Views in eTrials® allow you to see and check patient's main data related to a specific clinical trial. In these views it is possible to display values from fields coming from different forms.

To access this function you simply need to click the *Views* (A) key in the Homepage.

CONTINUES ►

 The Views key (A) is visible only if at least one view for the given study is present and active.



After having selected the Views key from the Homepage, the system shows the search pane (I), in which the appropriate clinical trial has already been selected.

In the drop-down menu field (A) you will find the active views for the selected clinical trial.

[CONTINUES ►](#)

Patients	Informed consent	Date informed consent	Date first dose	Date last dose	Daily dose	Blasts
33833138	1 yes ✓	26/08/2013 ✓	27/08/2013 ✓	19/09/2013 ✓	2,5 mg ✓	48 % ✓
38507820	1 yes ✓	19/09/2013 ✓	19/09/2013 ✓	19/09/2013 ✓	2,5 mg ✓	37 % ✓
45271279	1 yes ✓	01/08/2013 ✓	06/08/2013 ✓	23/08/2013 ✓	2,5 mg ✓	31 % ✓
49576546	1 yes ✎	31/10/2013 ✎				

Once the view has been selected, the system shows the table (I) where it is possible to set search filters according to the following criteria:

- Clinical Trial: in the drop-down menu the system shows the clinical trials to which the Investigator has been associated.
- View: a drop-down menu that allows you to select the appropriate view.
- Group: the system shows the groups to which the Investigator has been associated.
- Date or dates interval of the CRF: last change, opening, closure, validation, rejection, event.
- Patient: patient's reference code.
- Form status: not yet closed, closed and signed, validated, rejected.

The first column of the view (II) shows the identification codes of patients, which can be selected to filter the results of the views for that given user.

By selecting each single value in the columns after the first one, the list of present data is displayed; and selecting these the appropriate form gets opened.

END OF SUBJECT ■

 To be able to create the views and/or implement related filter, the operator needs to be authorized and to have at least a level 2 access (read and write).

INVESTIGATOR'S USER GUIDE



2.3 Planner

The Planner is a productivity tool of the *Patients* function. It graphically displays the state of progress of a given study with all enrolled patients. It allows selecting their appropriate forms with their status (not yet closed, closed and signed, validated, rejected).

To access the Planner you simply need to click the *Planner* button in the Homepage (A). The Planner of the clinical trial for which the appropriate key has been pressed is displayed.

CONTINUES ►

The screenshot shows the 'Clinical Trials: Planner' window for 'DEMO Fase I - eTrials DEMO Fase I'. The interface includes a 'Close' button, a 'Refresh' button, and a 'Status' filter section with options: not yet closed, closed and signed, validated, and rejected. The main table lists 6 patients with columns for 'CHK', 'BAS', 'DOSE LEVEL 1' (IND C1, VAL C1, CONS C1), 'DOSE LEVEL 2' (IND C1, VAL C1, CONS C1), 'FU', and 'OFF'. Callouts A-E point to the 'Groups' dropdown, the 'Status' filter, the patient ID column, the 'CHK' column, and the status icons respectively.

Patients (6)	CHK	BAS	DOSE LEVEL 1			DOSE LEVEL 2			FU	OFF
			IND C1	VAL C1	CONS C1	IND C1	VAL C1	CONS C1		
25427224	5 crf	✓	✓	✓	✓				✓	
28352333	9 crf	✓	✓	✓	✓				✓	
29536110	6 crf	✓✗	✓	✓						✓
44484383	1 crf	✓								
47118355	3 crf	✓				✓		✓		
63203713	4 crf	✓				✓	✓		✓	

After having selected the Planner button, the window here depicted will be shown.

From this window you can have a general overview of how study patients are doing.

In case the operator belongs to more than one group, you can select the appropriate one (A). You can also search per Patient (B) or per Form status (C).

In the first column to the left, you can see Patient's codes and in the following ones the present forms and their status.

In the line identifying the patient (D) it is possible to select each status icon and, thus, automatically open the appropriate CRF.

END OF SUBJECT ■

 By selecting the icon (E) you can immediately create a new form for that patient, directly from the Planner.

CHAPTER 3

PATIENTS

The screenshot displays the eTRIALS web application interface. The browser address bar shows 'www.sinaptica.it/clinicaltrials/ - ClinicOnline: eTrials'. The interface is divided into several sections:

- Navigation Area (I):** Located on the left, it includes a home icon, a user profile icon for 'Dr. Mario Rossi', and buttons for 'Template', 'CRF', 'CLINICAL TRIALS', 'QUERY', 'FORUM', and 'ADDRESS BOOK'. A callout 'A' points to the 'Patients' icon in the navigation area.
- Info Bar:** At the top, it shows 'Clinics online: 3' and a 'New Patient Registration' button. A callout 'B' points to this button.
- Study Sections:**
 - DEMO Phase I - eTrials DEMO Phase I:** Shows 2 groups (Bologna: 5 pat, 16 crf; Roma: 2 pat, 7 crf), 8 patients, 23 CRFs, and 3 queries. A callout 'I' points to the top navigation area.
 - DEMO LAL - eTrials DEMO Studio LAL:** Shows 1 group (Bologna: 1 pat, 1 crf), 3 patients, 1 CRF, and 0 queries.
 - DEMO Oss - eTrials DEMO Studio Osservazionale:** Shows 2 groups (Bologna: 4 pat, 10 crf; Roma: 4 pat, 21 crf), 8 patients, 31 CRFs, and 3 queries.
- Bottom Bar:** Shows '2 new queries'.

3.1 How to register a Patient

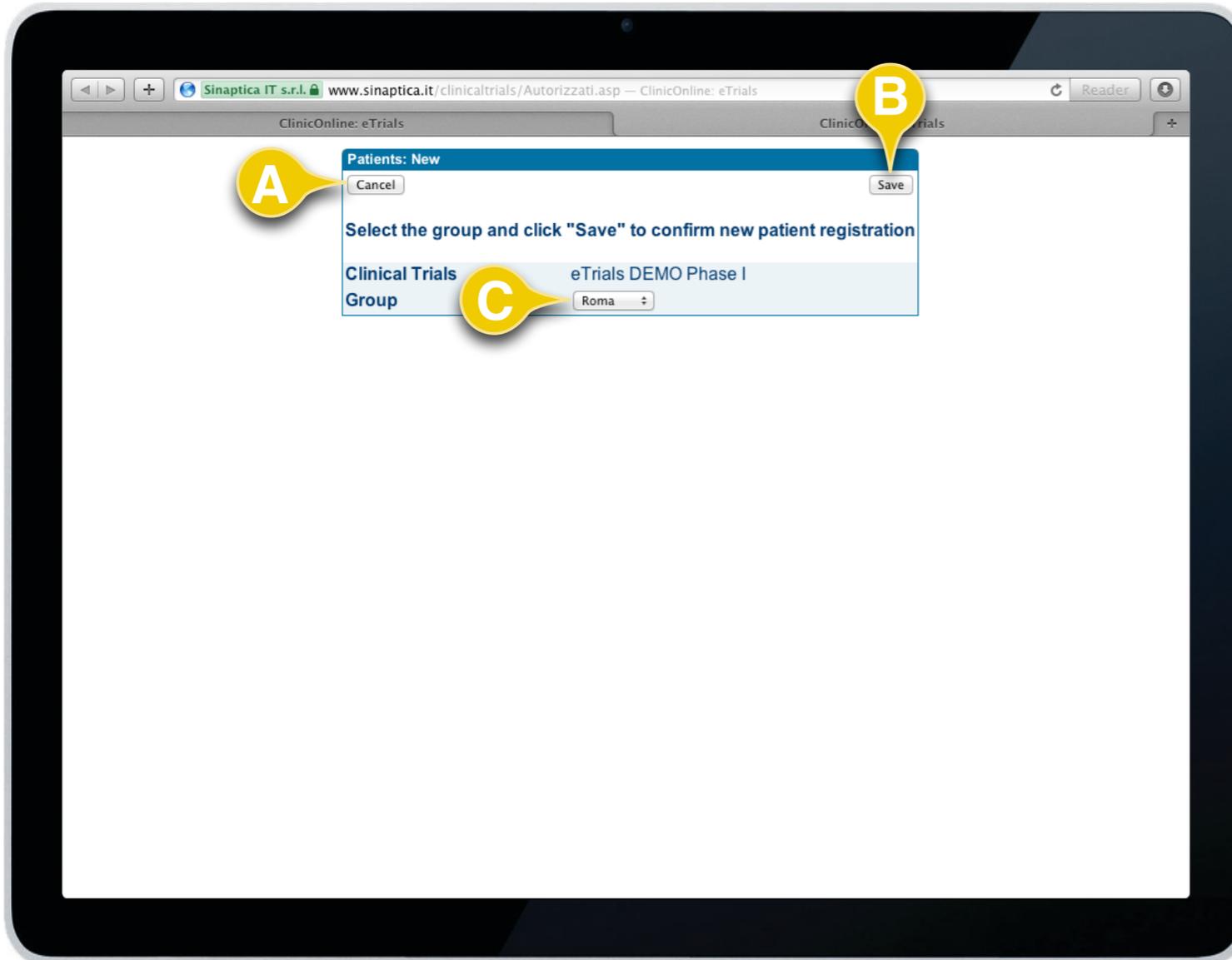
A new Patient can be registered in two different ways:

1. Through the *New Patient Registration* function button (B) within the operational area (II).
2. Selecting the *Patients* key (A) in the Menu area within the navigation area (I).

The first method allows you to register a Patient by immediately associating him or her to a given clinical study.

The second, allows you to do this once after you have registered the Patient.

CONTINUES ►



After having selected the *Register New Patient* function button in the Homepage, the system shows the Patients: New pane.

This pane allows you to:

- State the group to which the patient belongs (C).
- Cancel the operation (A).
- Save the information and go on with the registration (B).

[CONTINUES ►](#)

 It can be noticed in the window that the clinical trial has already been automatically associated, having chosen the fast registration procedure from the Homepage for the given study.

The screenshot shows a web browser window displaying the 'Patients: Form' interface. The form includes the following elements:

- Buttons:** 'Close', 'Create New Form', and 'Save'.
- User ID:** A text field containing '74678933' and a corresponding barcode.
- Name and Family name:** Text fields both containing 'A. (anonymous)'. A 'Badge MEMO' link is visible next to the Name field.
- Users groups:** A dropdown menu showing '[CO*] 458677 - Roma' and a 'Select to add' button.
- Clinical Trials:** Two dropdown menus, one showing 'eTrials DEMO Phase I' and another with 'Select to delete'.

Once we have selected the function button Save in the previous screen, the system automatically proposes the Patient's contact details where the appropriate numerical Code is given (**A**). This code is unique to this patient in the whole system. The wording A. A. is used instead of the patient's name and family name so as to keep privacy and anonymity in the platform.

Furthermore, this window allows you to complete the profile of the new Patient by filling in further data according to the operator's privileges:

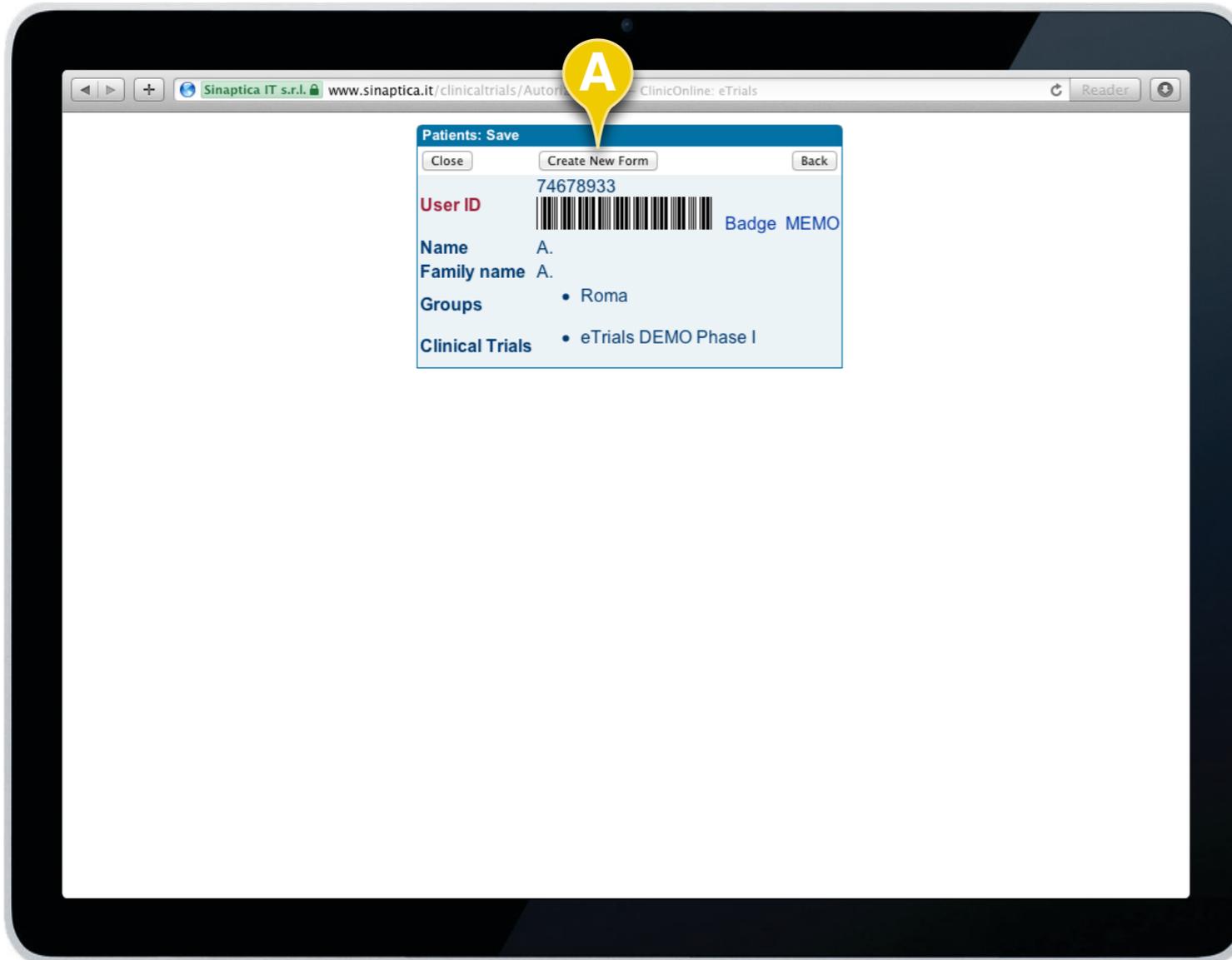
- Linking a Patient to other Groups (**B**).
- Linking the Patient to one or more Clinical Trials (**C**).

From this form it is already possible to create a new form for the given Patient (**E**).

Once these operations have been completed, you can close the window by using the *Close* function button (**D**).

CONTINUES ►

 The operator with access level 4, that is with administrator's privileges, has the possibility to manage the patients access to the platform.



Selecting the Save function button in the previous window, you will see the image on the side that sums up the information entered for the Patient.

The previously entered name and family name are left out for privacy reasons and will not be registered in the system.

From this window as well, it is possible to directly and easily create the forms foreseen in the study flow without any further steps, thanks to the *Create New Form* function button (A).

END OF SUBJECT ■

The screenshot shows the eTrials Investigator's User Guide interface. The browser address bar displays 'www.sinaptica.it/clinicaltrials/ - ClinicOnline: eTrials'. The interface is divided into a navigation sidebar on the left and a main content area. The sidebar includes a 'Dr. Mario Rossi' profile, a 'help desk' icon, and buttons for 'Home', 'Patients', 'Template', and 'CRF'. The main content area is titled 'Info' and displays three clinical trials:

- DEMO Phase I - eTrials DEMO P**: Clinical Trials online: 3. Groups: 2 (Bologna: 5 pat, 16 crf; Roma: 2 pat, 7 crf). Patients: 8 (33833138: 3 crf; 38507820: 4 crf; 45271279: 4 crf; 49576546: 1 crf; 65171639: 4 crf). CRF: 23 (not yet closed: 0; closed and signed: 7; validated: 16; rejected: 0). Query: 3 (to read: 0; to answer: 1; answered: 2).
- DEMO LAL - eTrials DEMO Studio LAL**: Clinical Trials online: 3. Groups: 1 (Bologna: 1 pat, 1 crf). Patients: 3 (74407021: 1 crf; 93067299: 0 crf; 96915261: 0 crf). CRF: 1 (not yet closed: 1; closed and signed: 0; validated: 0; rejected: 0). Query: 0.
- DEMO Oss - eTrials DEMO Studio Osservazionale**: Clinical Trials online: 3. Groups: 2 (Bologna: 4 pat, 10 crf; Roma: 4 pat, 21 crf). Patients: 8 (11206795: 1 crf; 12624031: 5 crf; 23143441: 1 crf; 29711892: 18 crf; 61095711: 1 crf). CRF: 31 (not yet closed: 17; closed and signed: 9; validated: 0; rejected: 5). Query: 3 (to read: 0; to answer: 1; answered: 2).

Callouts (I, A, B) highlight the navigation area, a patient count, and the Patients key respectively.

3.2 How to search a Patient

eTrials® allows you to search a given Patient among all the patients to which an operator can access in a fast way.

You can do this in two different ways:

1. Directly from the Homepage where all patients per study are shown (A).
2. Selecting the *Patients* key (B) in the navigation area (I).

You can search one Patient or a group of patients to access their Patients' form or to their CRFs.

By directly taping the Patient's code in the Homepage you can access the window that allows you to see all forms linked to him/her.

CONTINUES ►

i To see all patients to which an operator can access you only need to select the button *Patients* (B) in the navigation area and search without any filter, by selecting the *Search* function button.

The screenshot displays the eTrials web application interface for searching a patient's CRFs. The interface is divided into several sections:

- Left Sidebar:** Contains user information for Dr. Mario Rossi, navigation buttons (Home, Profile, Template, CRF), and menu options (CLINICAL TRIALS, QUERY, FORUM, ADDRESS BOOK). A notification indicates "2 new queries".
- CRF Search Panel (I):** Shows the patient's code (45271279), name (A. A. (patient)), and the clinical trial name (DEMO Phase I - eTrials DEMO Phase I). It includes a "Planner" section with a "Timeslot" grid and a "Form" section with filters for Group, Clinical data item, Status, and Download File. The "Status" section includes checkboxes for "not yet closed", "closed and signed", "validated", and "rejected". The "Download File" section includes a checkbox for "digital signature". The "VIEW OPTIONS" section includes a "Sort 1st by" dropdown and checkboxes for "Comments", "Correct", "Values", and "Attachments". The "Mode" section includes radio buttons for "PDF" and "Correction".
- Results Panel (III):** Shows a table of results with columns for "Form" and "Date". The first result is "CONSOLIDATION LEVEL 1 CYCLE 1 (Roma)" with a date of "19/9/2013" and a status of "19/9/2013 14:22 (closed) Rossi Dr. Mario".

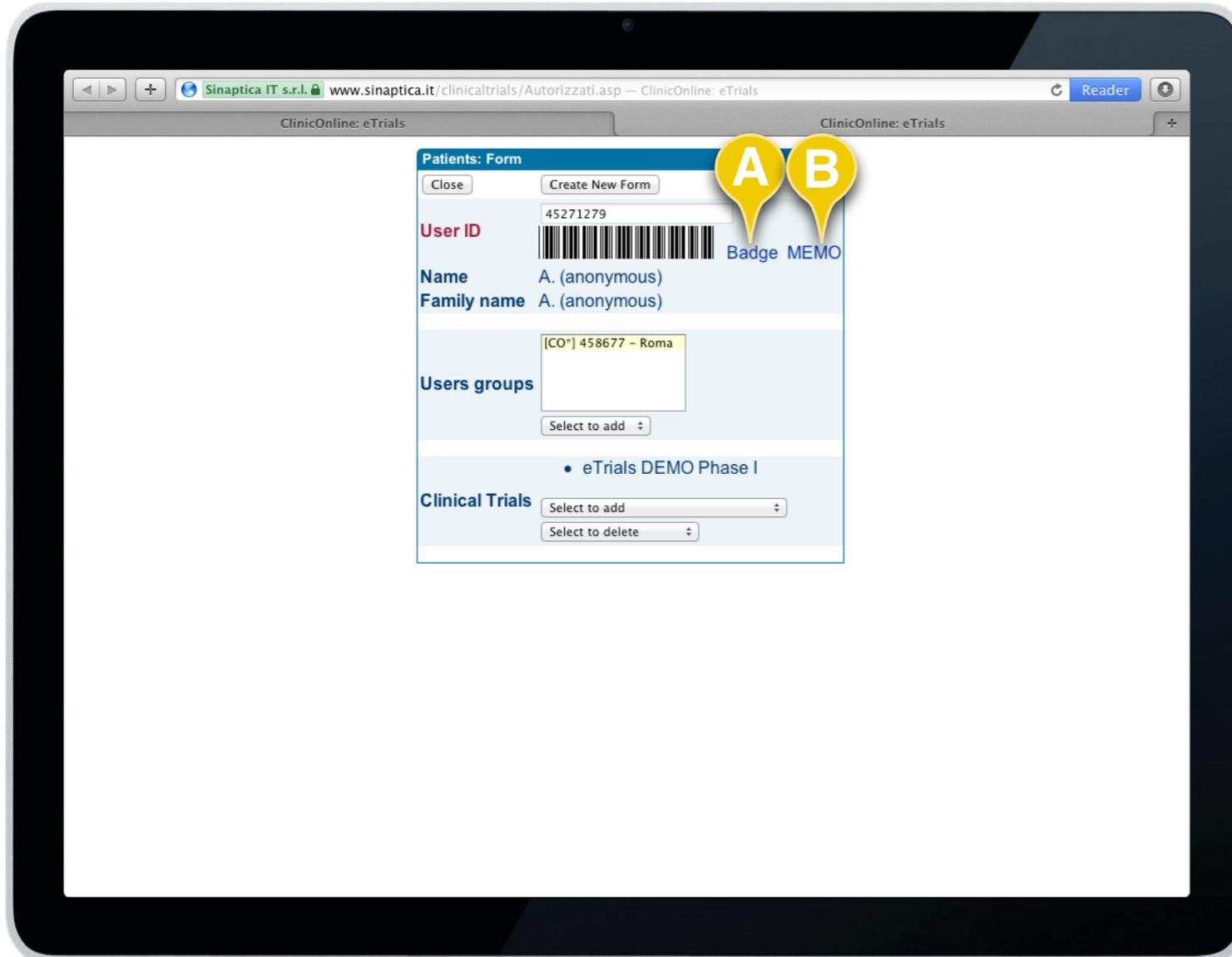
Callouts A, B, I, and III highlight specific features: A points to the "New Form" button, B points to the "Planner" section, I points to the search filters, and III points to the results table.

After having selected the patient's code, in the previous windows, eTrials® shows a pane with the following (I):

1. Patient code.
2. The possibility of creating a new form (A).
3. The Patient's CRF TimePlan (B).
4. The window to search CRFs (II) with different filters (e.g. by form, group, etc.).

In the Results pane (III) the system shows all forms searched and associated to the patient with their status and the possibility of opening the CRF and/or creating a PDF version.

END OF SUBJECT ■



3.3 How to manage a Patient in the system

eTrials® allows you to manage a Patient through the appropriate contact details pane. The operations allowed are: assigning/deleting Groups and Clinical Studies to which the operator belongs.

Once the desired Patient has been found through the procedure reported in paragraph 3.2 (How to search a Patient), you can access the Patients: Form pane that allows you to see - and when allowed, to modify studies and groups to which the patient has been associated.

The *Badge* link (A) next to the bar code shows a Patient identification badge, which can be printed out.

The system puts the *Memo* tool at the Investigator's disposal (B). Clicking on Memo the system puts at hand (so as to open or save, according to your computer preferences) an Excel file (.xls) containing the patient's information.

END OF SUBJECT ■

CHAPTER 4

CRF

The screenshot displays the eTrials Investigator's User Guide interface. The left sidebar contains navigation buttons: Home (A), Patients (B), CRF (C), and a menu with options like 'CLINICAL TRIALS', 'QUERY', 'FORUM', and 'ADDRESS BOOK'. The main content area shows three trial panels:

- DEMO Phase I - eTrials DEMO Ph...**: Shows 3 clinical trials online. Callout D points to the 'Patients: 8' section, and callout E points to a patient code (33833138).
- DEMO LAL - eTrials DEMO Studio LAL**: Shows 1 clinical trial online. Callout C points to the 'CRF' key.
- DEMO Oss - eTrials DEMO Studio Osservazionale**: Shows 2 clinical trials online. Callout D points to the 'Patients: 8' section.

Each panel includes a 'New Patient Registration' button, a 'Groups' count, a 'Patients' list with codes, a 'CRF' count, and a 'Query' count. The 'Patients' list for DEMO Phase I includes codes like 33833138, 38507820, 45271279, 49576546, and 65171639. The 'DEMO Oss' panel includes codes like 11206795, 12624031, 23143441, 29711892, and 61095711.

4.1 How to insert a CRF

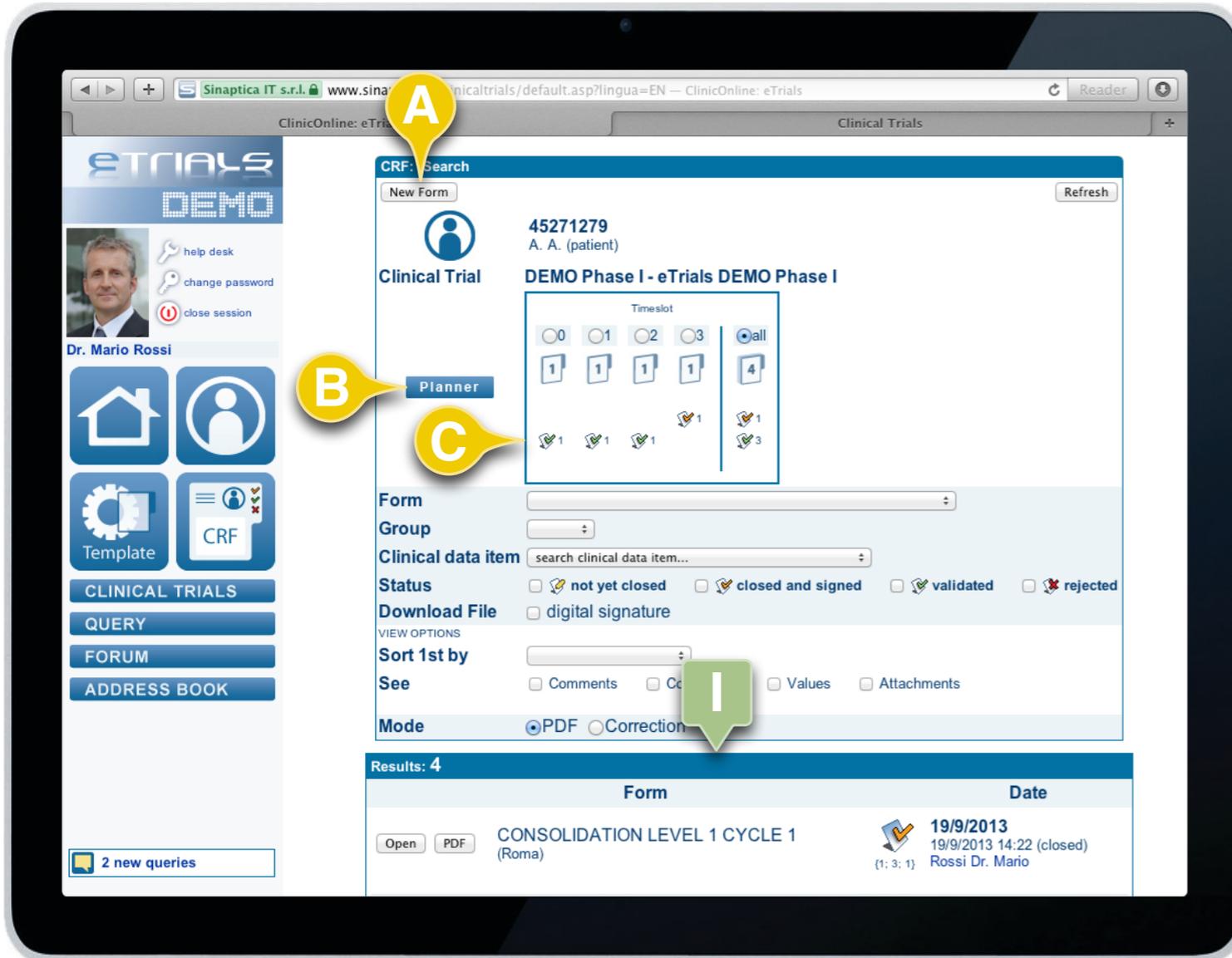
eTrials® offers three different ways to insert a CRF:

- Directly from the Homepage (A).
- From the *Patients* key (B).
- From the *CRF* key (C).

From the Homepage - If you are not actually seeing the Homepage, select the *Home* button (A) from the menu within the navigation area:

- The system shows you the list of active Patients (D) and their total number.
- You can simply select the Patient's code (E) to open a new CRF associated to that patient.

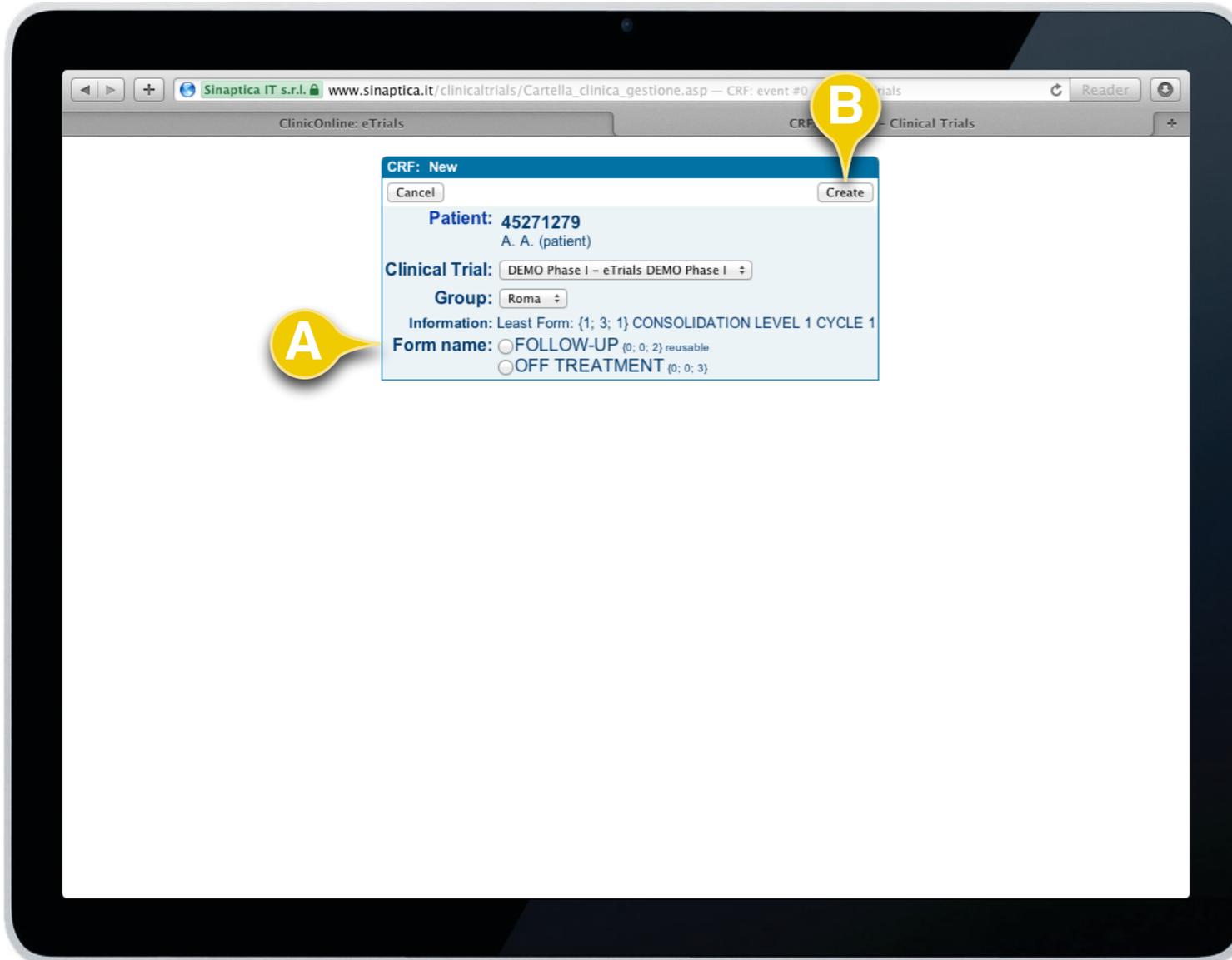
CONTINUES ►



In this window you will see a list of all forms (I) related to the selected patient and you may insert a new one selecting the *New Form* button (A).

There is a quick link to access the patient's *Planner* (B) as well as the *TimePlan* (C), which offers a summary of active forms and their status to ease management according to the study flow set up.

CONTINUES ►



Selecting the *New Form* button in the previous window, eTrials® displays:

- The identification details of the patient.
- The clinical trial in which he or she is enrolled.
- The group to which he or she belongs.
- The last form inserted for this patient.
- The only forms that can be inserted for this patient (A) according to the study flow.

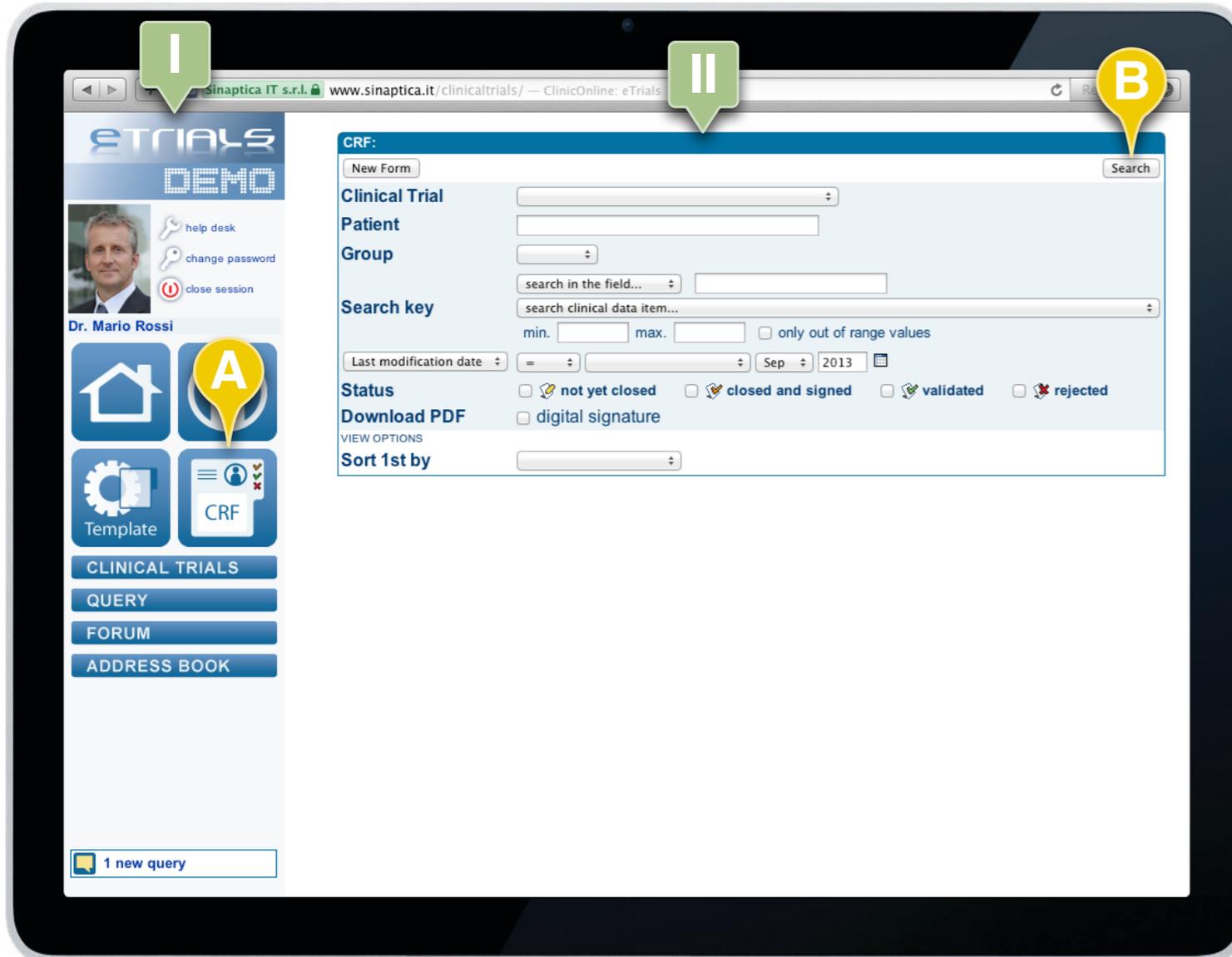
Once you have selected the form to be inserted, click the *Create* function button (B).

At this point, eTrials® allows you to fill in the form.

END OF SUBJECT ■

 Notice the list of forms. This window presents only the forms that you are able to create according to the study, its study flow and to the operators access permission.

INVESTIGATOR'S USER GUIDE



i To find all the CRFs to which a given operator can access, you simply need to press the function button Search (B) without selecting any filter.

👍 eTrials® lets you reorder results by: Patient, Form name, Event date, Opening date, Last modification date, Closure date. Besides, selecting the appropriate flags, it is also possible to visualize, in addition to the information that the system shows by default, potential Comments, Correction, Values and Attachments.

4.2 How to search a CRF

1. Selecting the CRF key (A) in the Menu area within the navigation area (I).
2. The system displays the CRF pane (II), where it is possible to set search filters according to the following criteria:
 - Clinical Trial: in this drop-down menu the system shows the clinical trials to which the Investigator has been associated.
 - Form: after selecting the study you can also select a form.
 - Patient: fill in the Patient's code you wish to find.
 - Group: in this drop-down menu the system shows the groups to which the Investigator has been associated.
 - Key search. It allows to filter CRFs according to:
 - Values and key words in the Form, Notes, Changes and Content (Form, Comments, Correction and Content), or according to an specific ID within the form.
 - Clinical data item (it is also possible to specify a range value).
 - Out of range values.
 - Dates or interval dates related to CRFs: event, opening, closing, last modification, validation or rejection.
 - Form status: not yet closed, closed and signed, validated, rejected.

3. Select the Search function button (B). The system shows the results in a pane called Results.

END OF SUBJECT ■

The screenshot displays the 'CRF: Search' interface in a web browser. The browser address bar shows 'www.sinaptica.it/clinicaltrials/'. The interface includes a search form with the following fields and options:

- Search Form:** Includes a 'New Form' button and a 'Search' button.
- Clinical Trial:** Dropdown menu with 'DEMO Phase I - eTrials DEMO Phase I' selected.
- Form:** Empty dropdown menu.
- Patient:** Empty text input field.
- Group:** Empty dropdown menu.
- Search key:** Includes 'search in the field...' and 'search clinical data item...' dropdowns, and 'min.' and 'max.' input fields with an 'only out of range values' checkbox.
- Status:** Checkboxes for 'not yet closed' (checked), 'closed and signed', 'validated', and 'rejected'.
- Download PDF:** Checkbox for 'digital signature'.
- VIEW OPTIONS:** Includes 'Sort 1st by' dropdown and 'See' checkboxes for 'Comments', 'Corrections', 'Values', and 'Attachments'.
- Mode:** Radio buttons for 'PDF' (selected) and 'Correction'.

The results table shows one result:

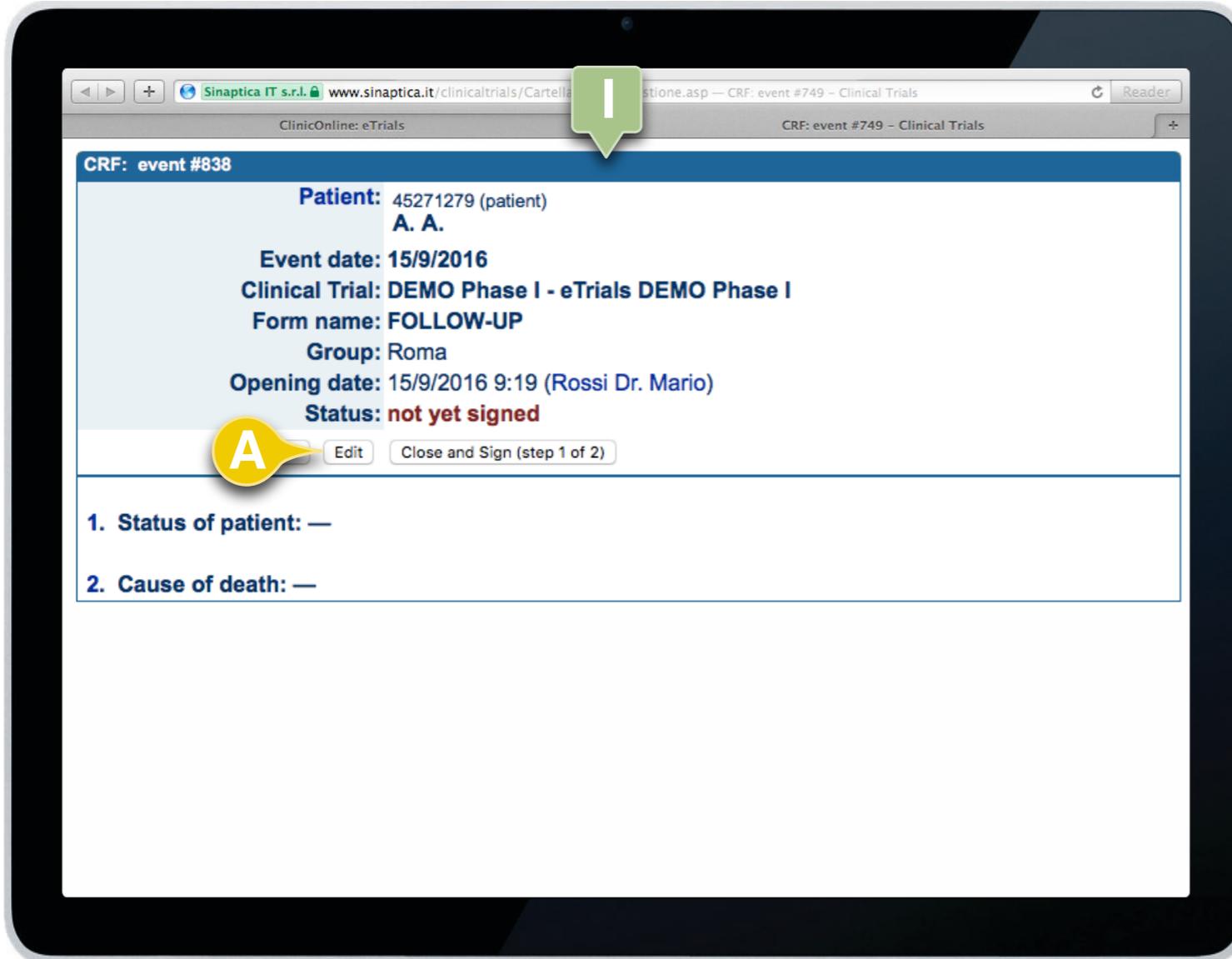
Form	Date
Open FOLLOW-UP A. A. (45271279) (Roma) (0; 0; 2)	30/10/2013 30/10/2013 12:22 (opened) Rossi Dr. Mario

4.3 How to fill in and close a CRF

You can complete and modify a CRF using the CRF: Form pane.

1. In the Results pane (I - see paragraph 4.2 on searching a CRF) select the *Open* function button (A) next to the form you want to work with. You can only fill in and close those forms that are open and marked with green in the appropriate window.
2. In each line of the Results list you can see the information related to each single form –e.g. the icon indicating its status (not yet closed, closed and signed, validated, rejected), the date of last operation done and the user who has done it (B).

CONTINUES ►



CRF: event #838

Patient: 45271279 (patient)
A. A.

Event date: 15/9/2016

Clinical Trial: DEMO Phase I - eTrials DEMO Phase I

Form name: FOLLOW-UP

Group: Roma

Opening date: 15/9/2016 9:19 (Rossi Dr. Mario)

Status: not yet signed

A Edit Close and Sign (step 1 of 2)

1. Status of patient: —

2. Cause of death: —

Once open, the form is displayed in a new window in the browser where the patient's information are shown, as well as the status of the form and related information (I).

To fill in the form you simply need to click the *Edit* function button (A).

[CONTINUES ►](#)

 The form fields are listed but do not state any value as they are empty.

The screenshot shows a web browser window displaying the 'CRF: Form' interface. The browser address bar shows 'www.sinaptica.it/clinicaltrials/Cartella_clinica_gestione.asp'. The form contains the following information:

- Patient:** 45271279 (patient) A. A.
- Clinical Trial:** DEMO Phase I - eTrials DEMO Phase I
- Form name:** FOLLOW-UP
- Group:** Roma
- Opening date:** 15/9/2016 9:19 (Rossi Dr. Mario)
- Last modified on:** no updates done

Below the form header, there are two sections with radio button options:

- 1. Status of patient**
 - ?
 - alive 1
 - death 2
 - lost to follow-up 3
- 2. Cause of death**
 - ?
 - infection 1
 - hemorrhage 2
 - toxicity 3

At the top of the form, there are three callout boxes labeled A, B, and C pointing to the 'View', 'Close and Sign (step 1 of 2)', and 'Save' buttons respectively.

The eTrials® system displays the CRF: Form pane. In this pane you can see the form values.

Once it has been filled in, the Investigator can:

- Select the **Save** function button (**C**): the forms will be saved, the CRF form can still be modified and, thus, by selecting the *Visualize* function button (**A**) you will go back to the pane CRF: event.
- Select the *Close and Sign (step1 of 2)* function button (**B**). In this case, the system verifies the checks which are present and eventually states any issue in the compilation.

[CONTINUES ►](#)

The screenshot displays a web browser window with the URL www.sinaptica.it/clinicaltrials/Cartella_clinica.asp. The page title is "CRF: Form". The form contains the following information:

- Patient:** 45271279 (patient) A. A.
- Clinical Trial:** DEMO Phase I - eTrials DEMO Phase I
- Form name:** FOLLOW-UP
- Group:** Roma
- comments:** (empty text area)
- Opening date:** 15/9/2016 9:19 (Rossi Dr. Mario)
- Last modified on:** 21/9/2016 11:44 (Rossi Dr. Mario)

At the top right of the form, there is a button labeled "Close and Sign (step 2 of 2)". A green callout bubble labeled 'I' points to the top of the form, and a yellow callout bubble labeled 'A' points to the "Close and Sign" button. Below the form, there are two sections of radio button options:

- 1. Status of patient**
 - alive 1
 - death 2
 - lost to follow-up 3
- 2. Cause of death**
 - infection 1
 - hemorrhage 2
 - toxicity 3

A yellow callout bubble labeled 'B' points to the first radio button in the "Status of patient" section.

If you have chosen the *Close and Sign (step 1 of 2)* function button, the system implements the foreseen checks according to the CRF template (runcheck) and, if positive, shows to the Investigator the whole CRF form in the CRF: Form pane (I) to further check the data.

To confirm closure of the CRF form, select the *Close and Sign (step 2 of 2)* (A).

CONTINUES ►

i When each value is filled in, the related field is automatically saved in the system, also registering the time and the user who has done the operation (B).

The system asks to further confirm the closure of the CRF; selecting *OK* (**B**) the form becomes unmodifiable.

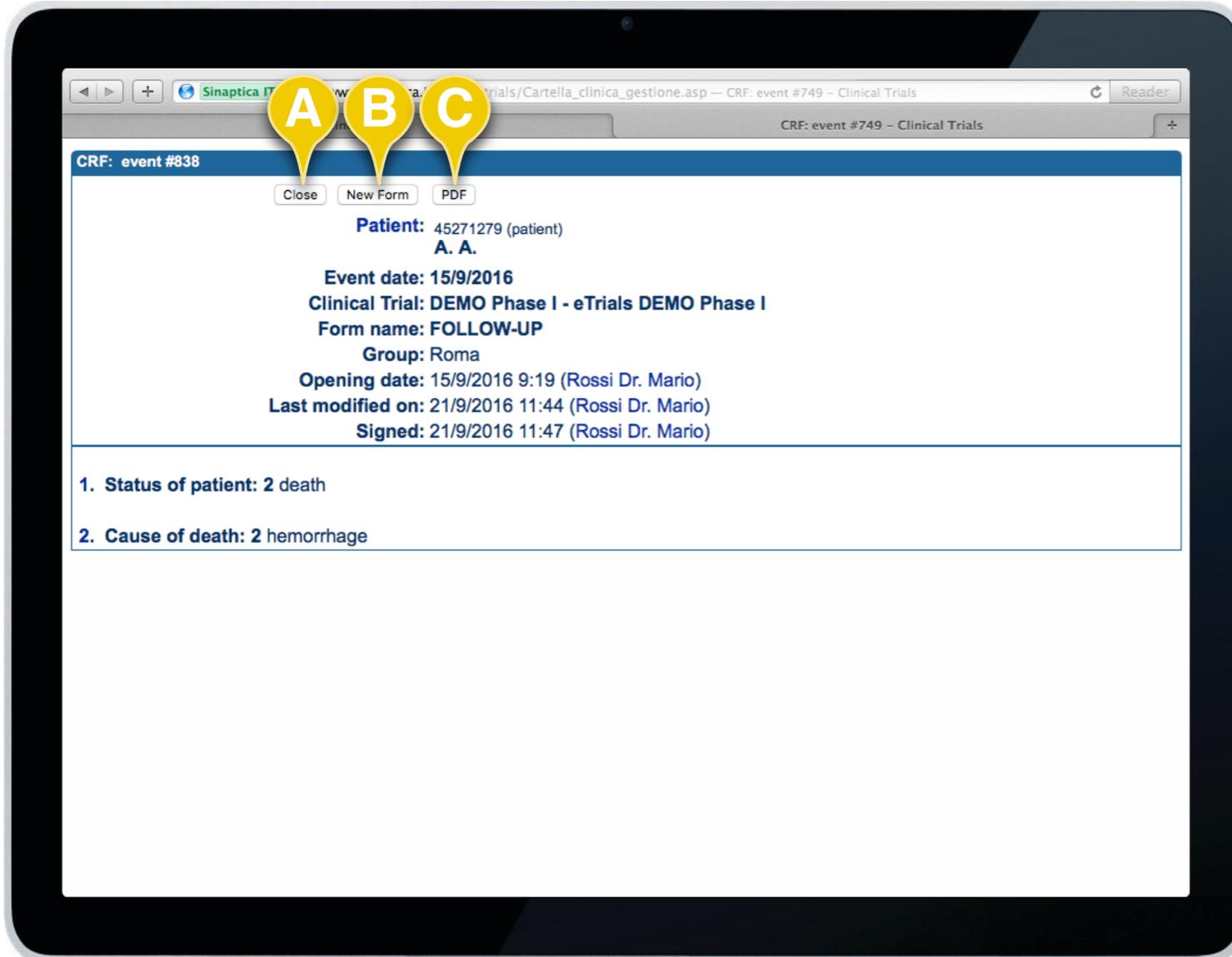
Selecting the *Cancel* function button (**A**), the form is not closed and, thus, you are still able to modify it.

CONTINUES ►

The screenshot shows a web browser window displaying a CRF form. The browser's address bar shows the URL: www.sinaptica.it/clinicaltrials/Cartella_clinica_gestione.asp. The page title is "CRF: Form". The form content includes:

- Patient: 45271279 (patient) A. A.
- Opening date: 15/9/2016 9:19 (Rossi Dr. Mario)
- Last modified on: 21/9/2016 11:44 (Rossi Dr. Mario)
- Section 1: Status of patient
 - alive 1
 - death 2
 - lost to follow-up 3
- Section 2: Cause of death
 - infection 1
 - hemorrhage 2
 - toxicity 3

A confirmation dialog box is overlaid on the form, asking: "Da 'https://www.sinaptica.it': Do you want CLOSE and SIGN the Form?". The dialog box has two buttons: "Annulla" (labeled **A**) and "OK" (labeled **B**). The "OK" button is highlighted in blue.



In case the form was closed and signed, the system does the following:

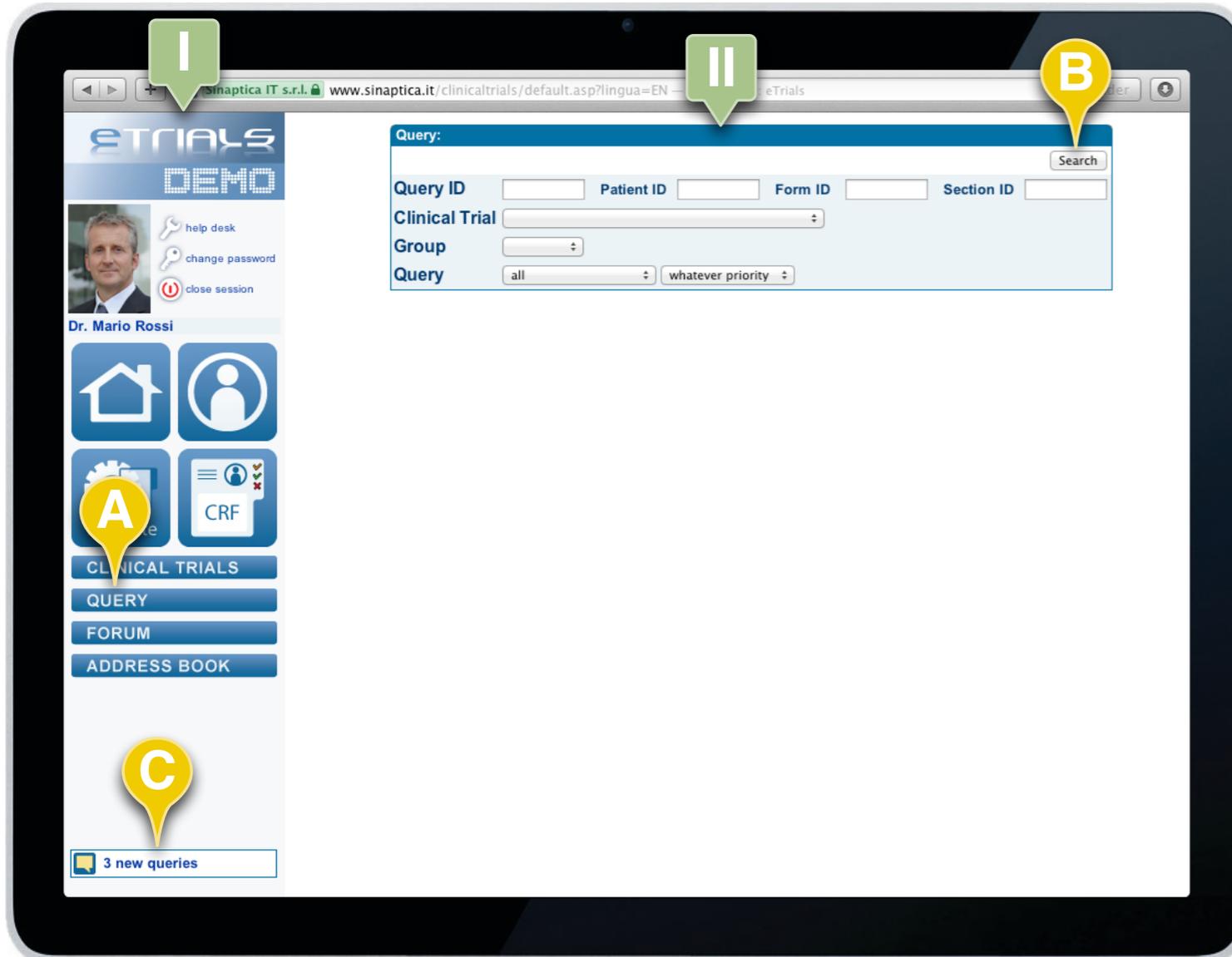
- If foreseen in the CRF Template, the system automatically sends the predefined information to, e.g. the Data Manager.
- Shows the CRF: Event pane and proposes the following actions:
 - *Close (A)*: closes the browser window and goes back to the main window.
 - *New Form (B)*: selecting this function button it is possible to create a new form if foreseen in the study flow (see chapter 4.1).
 - *PDF (C)*: does a PDF print of the CRF.

END OF SUBJECT ■

CHAPTER 5

QUERY

INVESTIGATOR'S USER GUIDE



5.1 How to search a Query

You can search a given query from the Query function.

1. Click on the *Query* (A) function in the navigation Area (I).
2. When the system shows the Query pane (II) you can set the following filters:
 - Query ID: query code.
 - Patient ID: Patient's code.
 - Form ID: form code.
 - Section ID: number of the potential field to be queried.
 - Clinical Study: clinical study to which the form belongs (if the investigator belongs to one single clinical study, this is already defined in the system).
 - Group: the Group to which the CRF Form is associated.
 - Form: form template (this option is available only if we have first selected the Clinical Trial).
 - Query: filters queries according to their status (all, to read, to answer, to read or to answer, answered) and to three different levels of priority.
3. Select the *Search* function button (B).



The navigation pane proposes a shortcut (C) to queries that have not been read or answered yet and indicates the total number and their status.



To find all the queries to which a given operator can access, you simply need to press the function button Search (B) without selecting any filter.

CONTINUES ►

The screenshot displays the 'Query: Search' interface. At the top, there is a search bar with fields for 'Query ID', 'Patient ID', 'Form ID', and 'Section ID'. Below this, there are filters for 'Clinical Trial' and 'Group'. The results pane shows three query entries. Each entry has a header with sender and recipient information, a date and time, and a status. The first two entries are yellow, indicating they are waiting to be read or answered. The third entry is white, indicating an answer has been sent. The first two entries have priority levels 1 and 2, respectively. The first entry has a 'View Query' button. The second entry has a 'View Query' button. The third entry has an 'Answer' button. The sidebar on the left contains navigation buttons for 'Home', 'Profile', 'Template', 'CRF', 'CLINICAL TRIALS', 'QUERY', 'FORUM', and 'ADDRESS BOOK'. A notification bar at the bottom left indicates '4 new queries'.

The system shows the elements found in the Results pane. The information regarding the given query are displayed in 4 columns:

The light icons (I) show the query status. Yellow light: waiting to be read or answered. White light: an answer has been sent. The number (1 to 3) refers to the priority level.

The *Query* function button (A) opens a window that allows you to edit and/or consult the content of the query.

Selecting the *Form* function button (B) the CRF related to the query gets opened.

The second column (II) shows the following information:

- Clinical Trial.
- Patient's ID.
- Group to which the Form is associated.
- Form name.
- Possible name of the field that has been queried.

In the header you will find the sender and the main addressees (which means the Investigator that has Closed and Signed the queried Form).

The third column (III) contains the text of the query. In the header you will find the date in which the question was created and read for the first time by one of the members of the Group.

The last column (IV) contains the answer to the query.

In the header you will find the date in which it was answered and by whom.

i In the results pane, next to the information: study name, patient, group, form name, section (in column II), you can mark the appropriate flag to select a filter and search specific queries.

END OF SUBJECT ■

The screenshot shows the eTrials web application interface. At the top, there is a search bar labeled 'Query: Search' with fields for Query ID, Patient ID, Form ID, and Section ID, and a 'Search' button. Below the search bar, there are dropdown menus for 'Clinical Trial', 'Group', and 'Query' (with options 'to read or to answer' and 'whatever priority').

The main content area displays a list of queries. The first query is highlighted with a yellow background and a callout 'A' pointing to the 'Query' button. The second query is also highlighted with a yellow background and a callout 'B' pointing to the 'View Query' button. The third query is not highlighted. The fourth query is highlighted with a yellow background and contains a narrative text: 'Good morning Dr. Rossi, I would kindly ask you to confirm that the date of the end of the cycle coincides exactly with the date of the start of the cycle.' and an 'Answer' button.

The sidebar on the left includes a user profile for 'Dr. Mario Rossi' and navigation buttons for 'CLINICAL TRIALS', 'QUERY', 'FORUM', and 'ADDRESS BOOK'. A notification at the bottom of the sidebar indicates '4 new queries'.

5.2 How to manage a Query

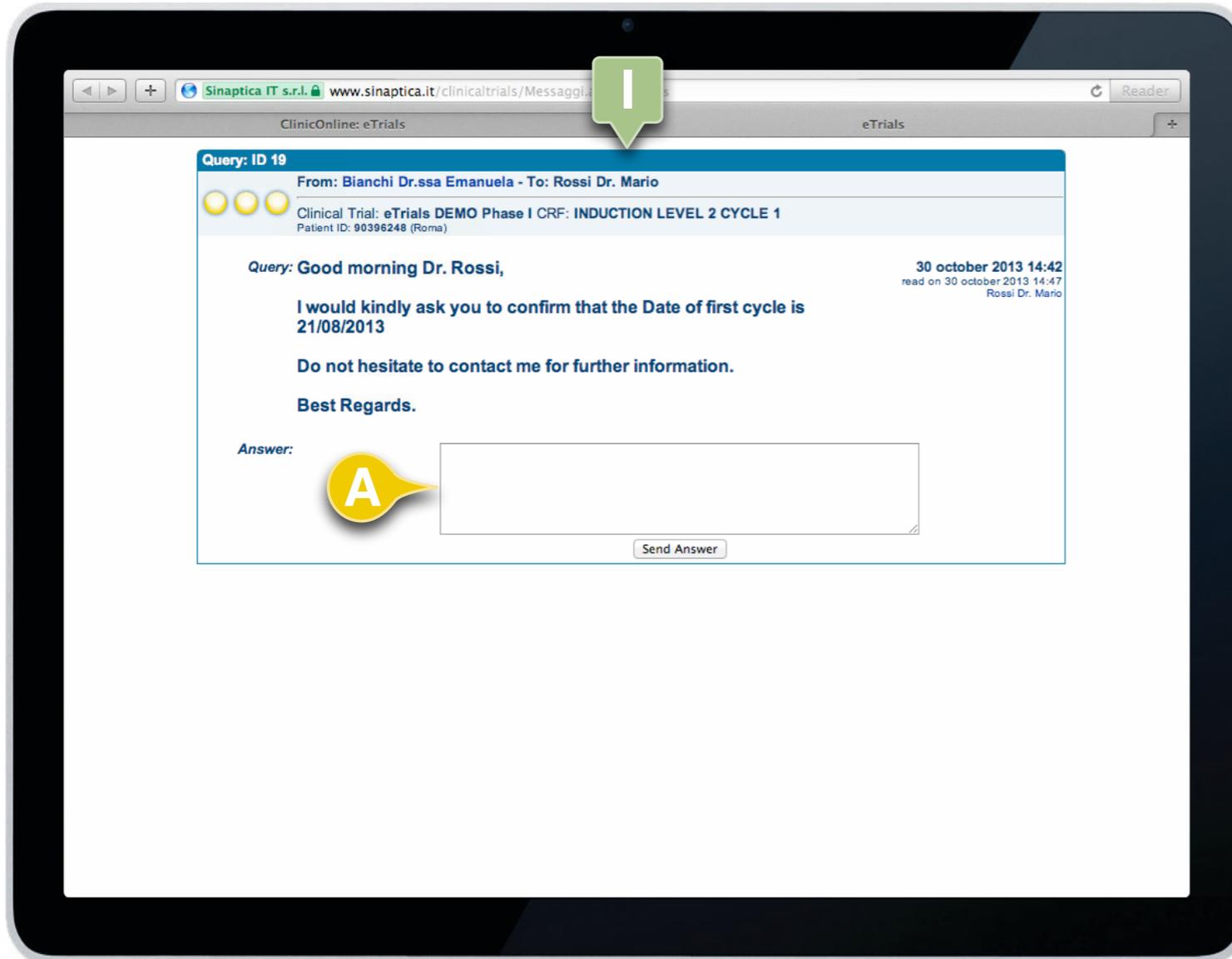
Queries are managed in the relevant section and the Investigator may do the following operations:

- Read.
- Answer.
- Check.

READ

Once you have searched for a given query (see *how to search a query on chapter 5.1*), to read the narrative select either the *Query* function button (A) or the *View Query* (B).

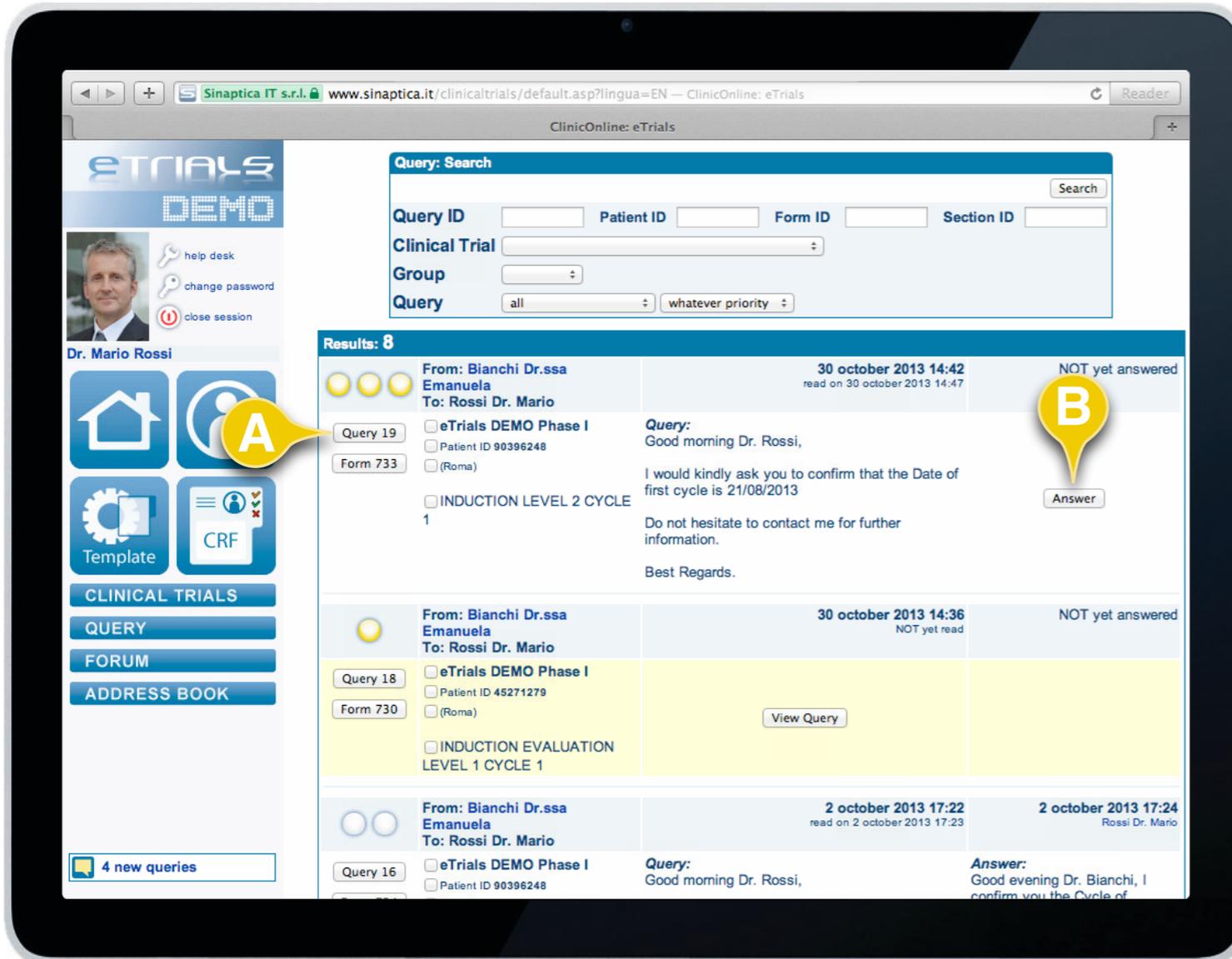
CONTINUES ►



The system opens a new window in the browser (I), in which the narrative of the Query is displayed.

The system already proposes a free text field to address it (A) and allows you to directly perform this operation as briefly described in the appropriate section.

[CONTINUES ►](#)



ANSWER

To answer the query select either the *Query* function key (A) or the *Answer* one (B).

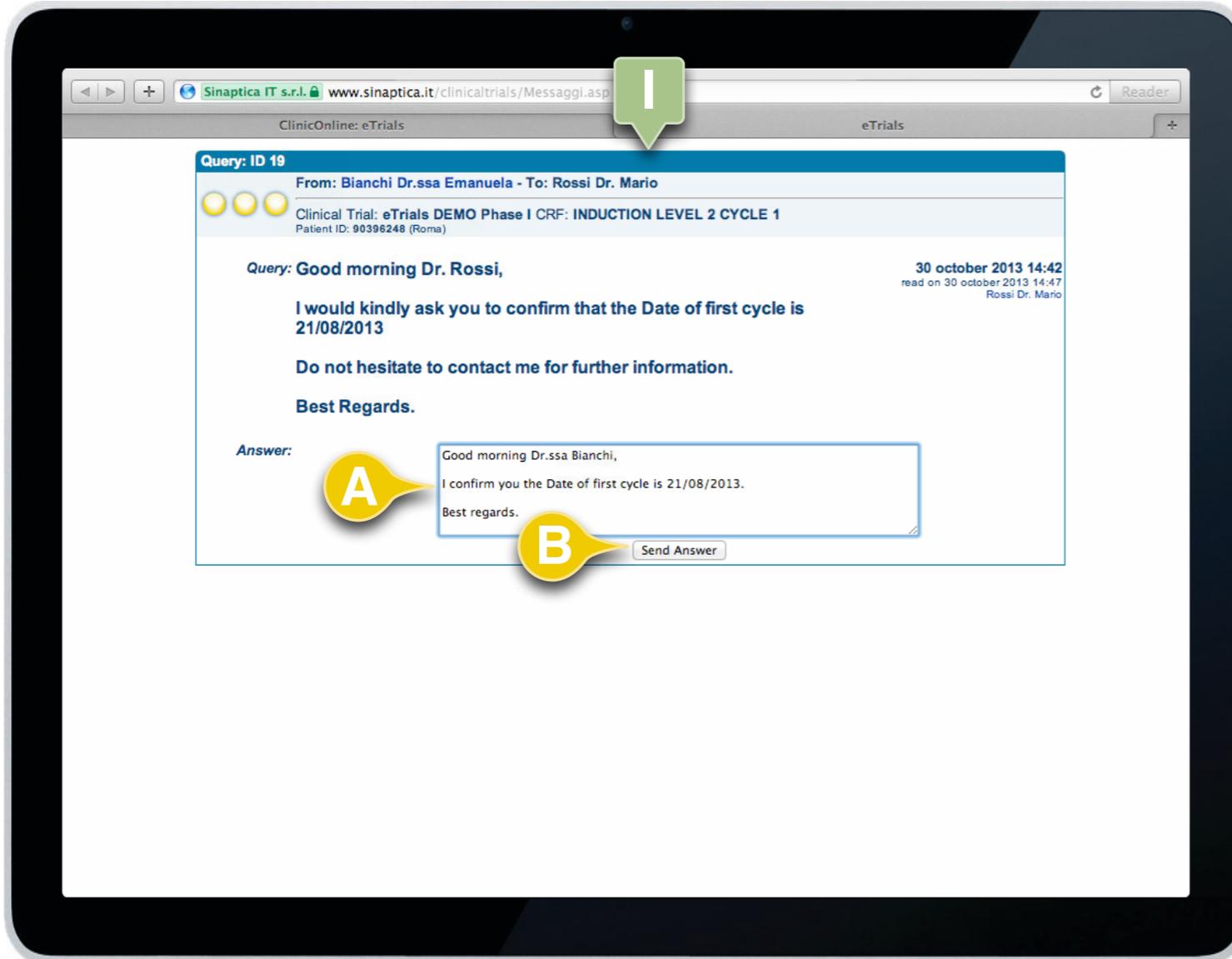
CONTINUES ►

i Once the Query has been read, the system updates the information by displaying the text of the Query; its back color changes from yellow to white.

The system opens a new window in the browser (I), in which you can see the query and a free text field (A) to answer it.

Once filled in, select the *Send Answer* function button (B).

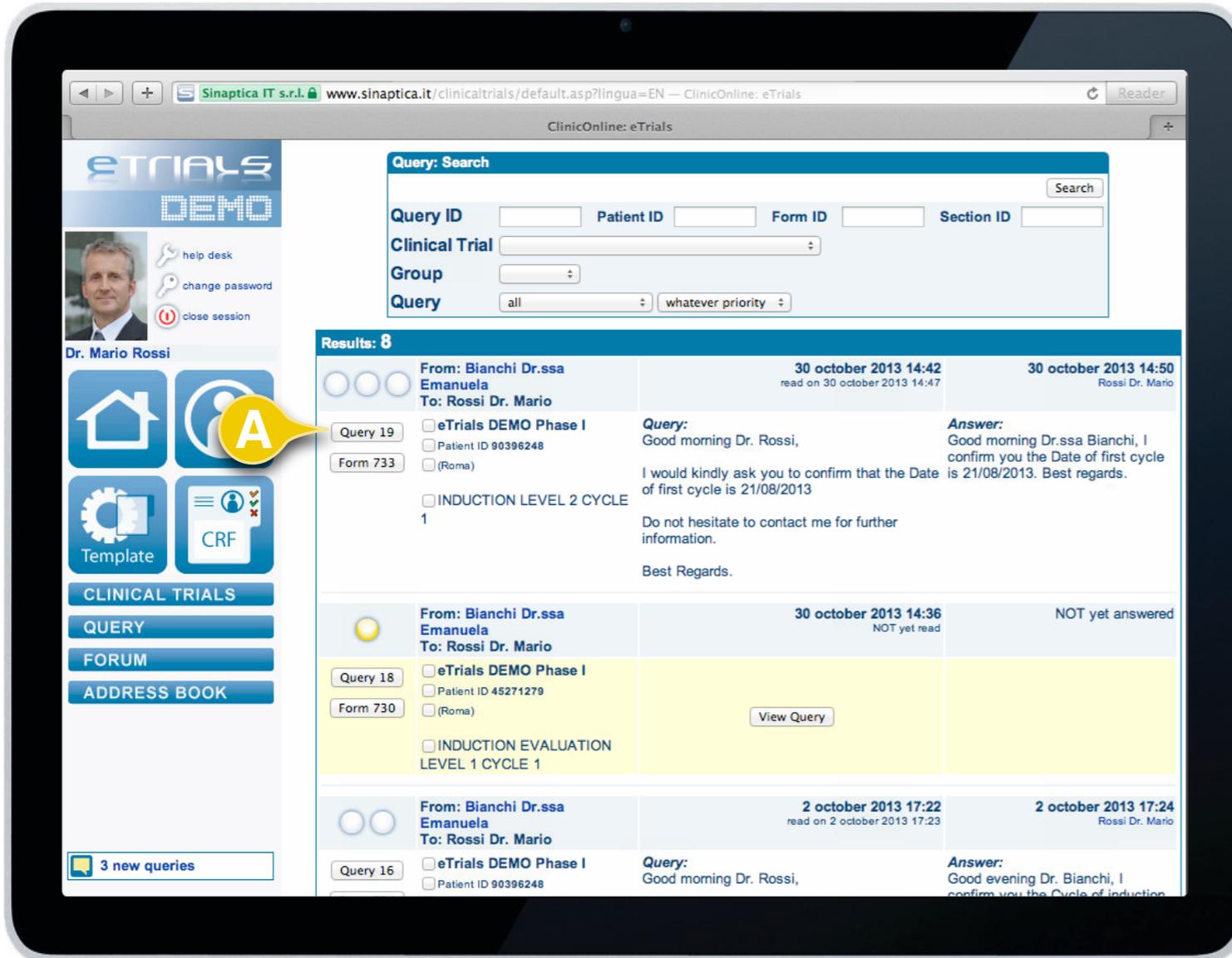
CONTINUES ►



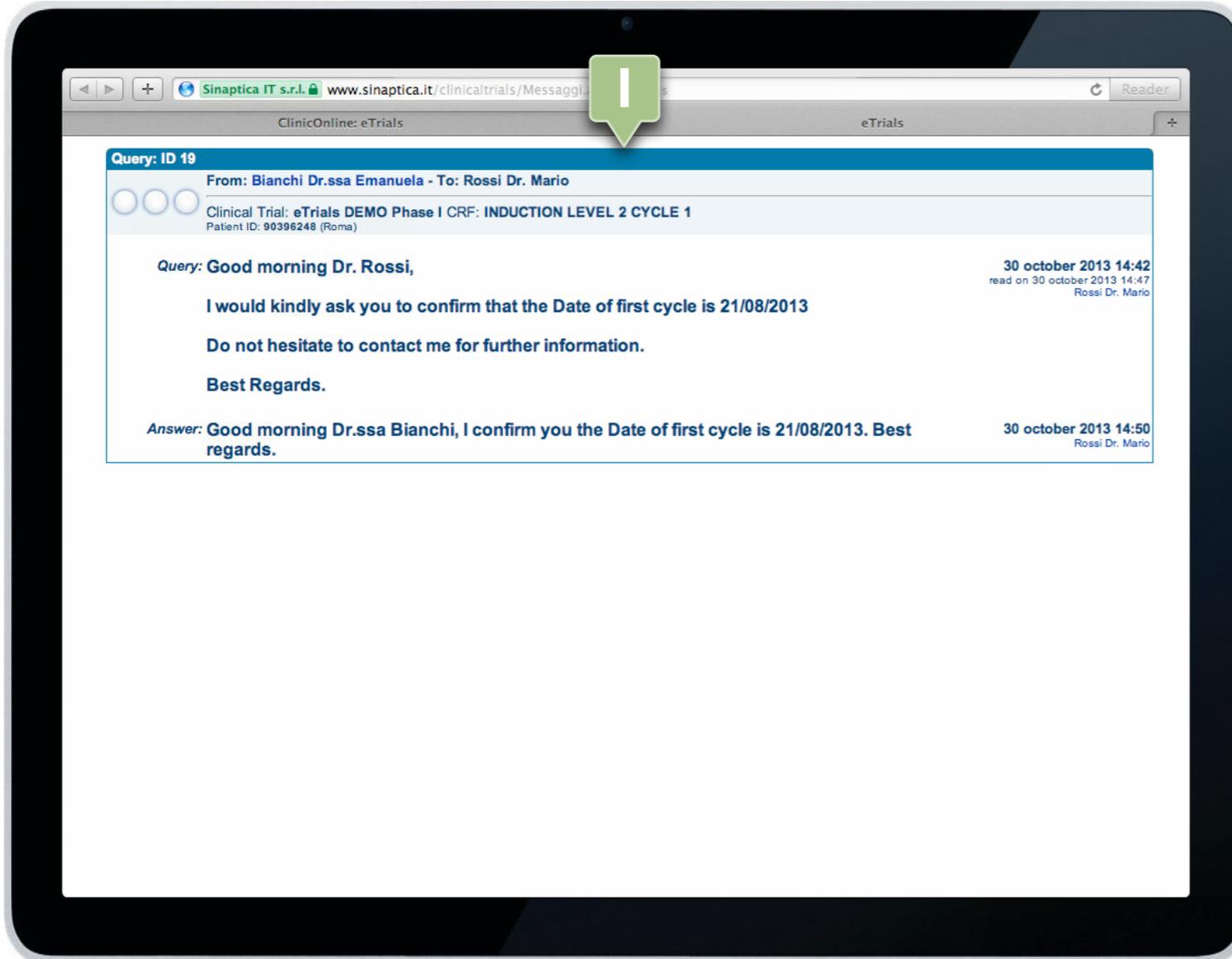
CHECK

To check the query select on the *Query* function button (A).

CONTINUES ►



i Once the answer to the Query has been sent, the system updates the status light icon (that goes from yellow to white) and displays both the query text and its answer. The header is then updated with the answer date and author.



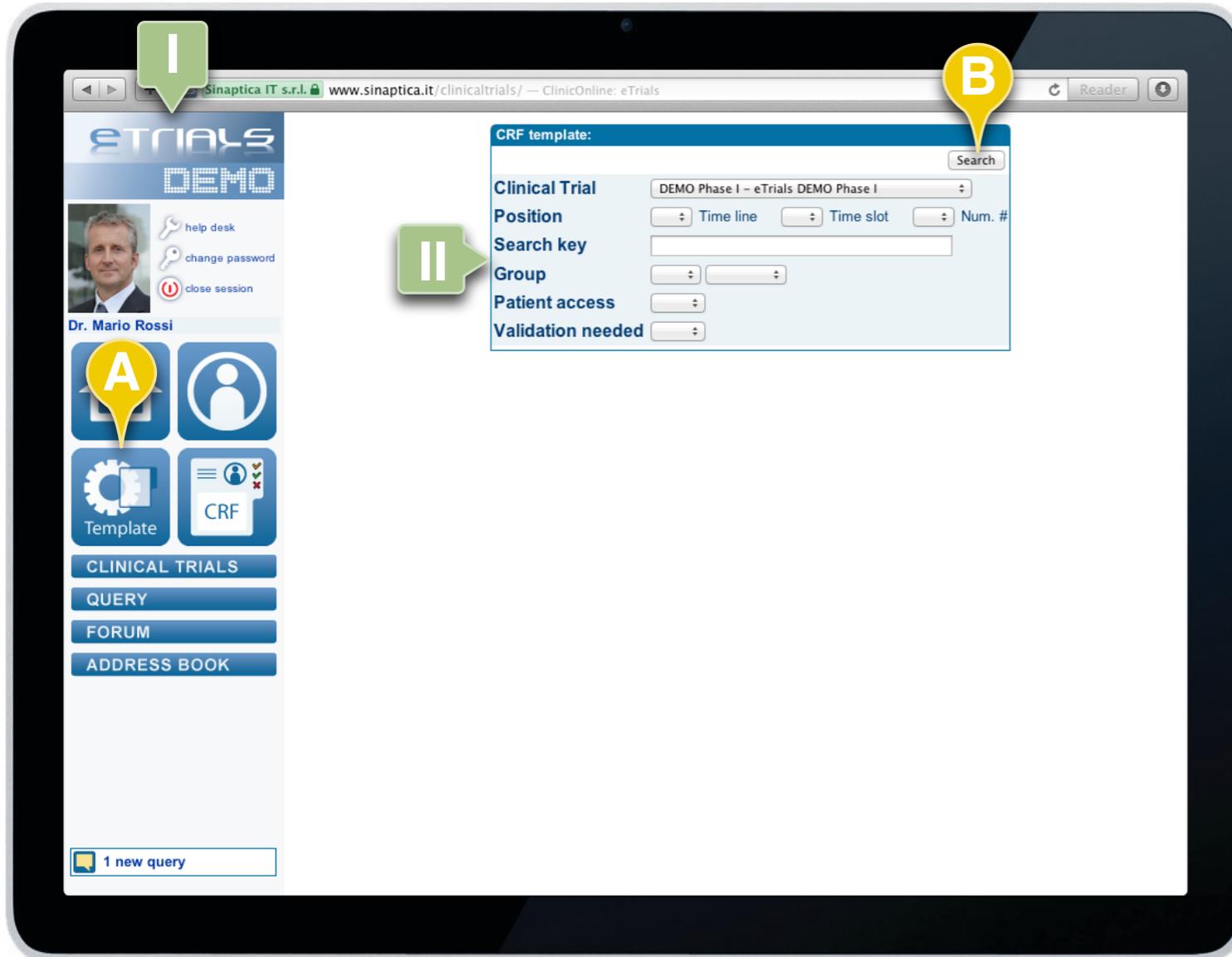
The system opens a new window in the browser (I), in which all the query related information are displayed:

- Main roles dealing with the query.
- Clinical study and possible field within the form to which the query refers.
- CRF to which the query is addressed.
- Patient and related group to which the query is addressed.
- Narrative of the query and related answer with added information on when these operations have been performed and by whom.

END OF SUBJECT ■

CHAPTER 6

CRF TEMPLATES



6.1 How to search a CRF Template

eTrials® allows searching for a given form among all available CRF Templates to which an Investigator has access, in a fast manner, using appropriate selection filters. You can search a template -or group of templates- to visualize the Template itself, to print it in PDF format or to check a Clinical Trial TimePlan.

1. Click on the *CRF Template* button (A) within the navigation area (I).
2. Select one or more filters within the CRF Template pane (II):
 - Clinical Trial: study to which the template is associated.
 - Position: template coordinates within the TimePlan.
 - Key search: free text search field.
 - Group: the group to which the template is associated.
 - May be used by the Patient.
 - Validation needed.
3. Select the *Search* function button (B).

CONTINUES ►

i You may search for a CRF Template without any predefined parameter. This way all CRF Templates that belong to the Investigator's group and to clinical trials to which he/she has been associated will be displayed.

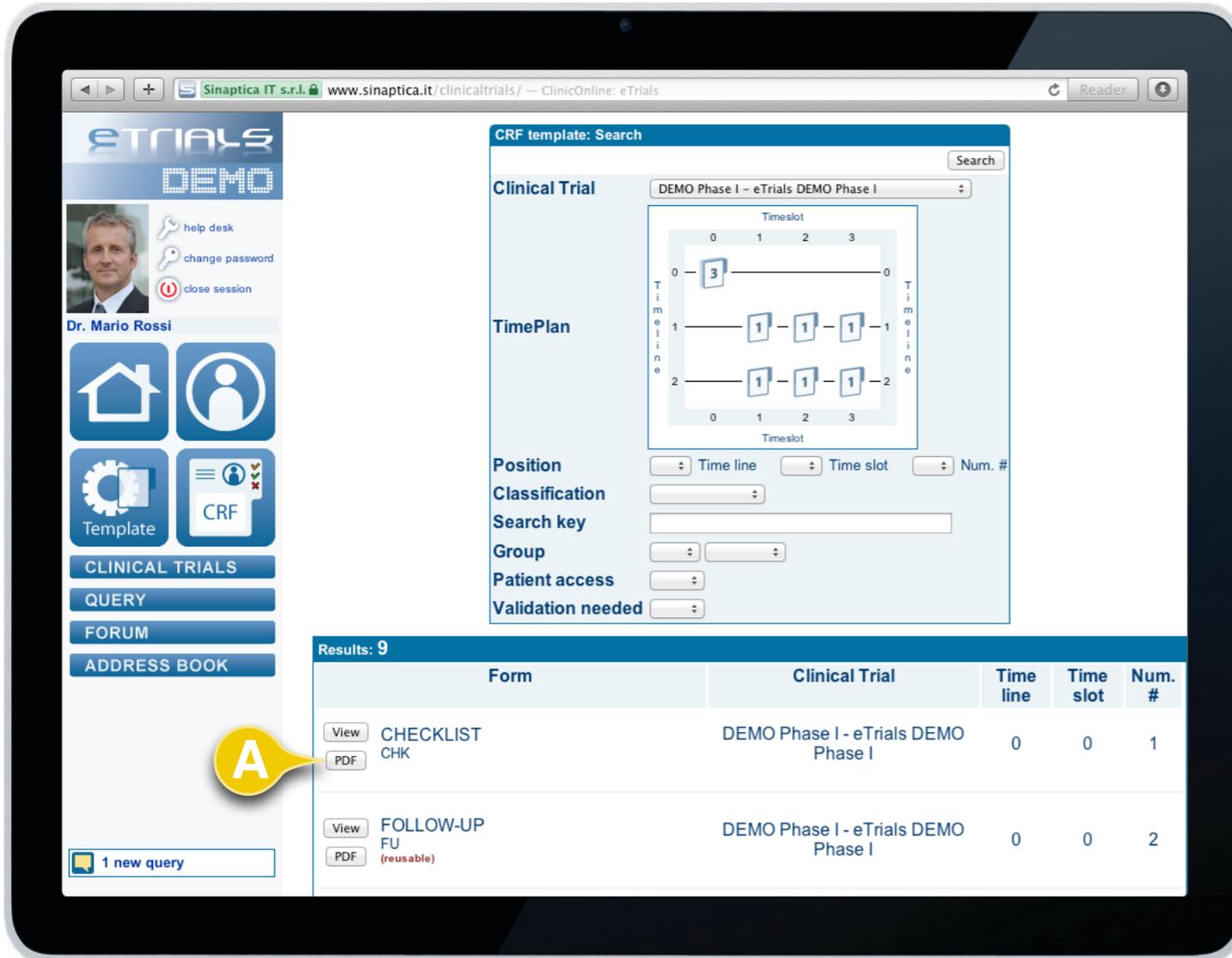
The system shows the results in the appropriate pane (I).

To visualize a given template, click on the *View* function button (A).

Once the clinical trial has been selected and the search performed, it is possible to see the TimePlan (B) that allows you to see the sequence of forms foreseen in the study.

END OF SUBJECT ■

i In case a Clinical Trial has been selected (or in case the Investigator is associated to only one Clinical Trial), the system graphically displays the TimePlan of the Clinical Trial (B). The icons represent the number of CRF Templates available for each combination Timeline/Timeslot; clicking on an icon the appropriate CRF Templates are searched and displayed.



6.2 How to print a CRF Template

To print CRF Templates, eTrials® adopts the PDF format. This format guarantees accurate editing, archiving, and sending documents in digital format.

To print the template in digital format select the *PDF* function button (A) in the line displaying the template in question.

The system saves the Template in PDF format in the appropriate folder according to the Investigator computer settings.

END OF SUBJECT ■

CHAPTER 7

CLINICAL TRIALS

INVESTIGATOR'S USER GUIDE

The screenshot shows the eTRIALS web application interface. On the left, there is a navigation menu with buttons for Home, Profile, Template, CRF, CLINICAL TRIALS, QUERY, FORUM, and ADDRESS BOOK. A search pane (I) is open, showing fields for Code, Clinical Trials, Group, and Sort by. Below the search pane, a results table (II) displays three clinical trials with columns for Form, Code, Clinical Trial, Start date, and End date. Callout boxes (A and I) highlight the search function and the search pane respectively.

Form	Code	Clinical Trial	Start date	End date
Planner	DEMO Phase I	eTrials DEMO Phase I	1/1/2009	31/12/2013
Planner	DEMO LAL	eTrials DEMO Studio LAL	1/10/2011	31/12/2013
Planner	DEMO Oss	eTrials DEMO Studio Osservazionale	1/10/2011	31/12/2013

7.1 How to search a Clinical Trial

The Investigator can access clinical trials selecting the *Clinical Trials* function button (A) on the left-hand side of the navigation area. With this operation, the system displays clinical trials to which the Investigator is associated.

In this window it is possible to search for a given Clinical Trial using the search pane (I) with the following parameters:

- Code: clinical trial code.
- Clinical Trial: study name.
- Group: allows you to search for a clinical trial according to a given group.
- Sort by: allows to order results by:
 - Clinical Trial.
 - Code.

The results pane (II) reports the following information for each study:

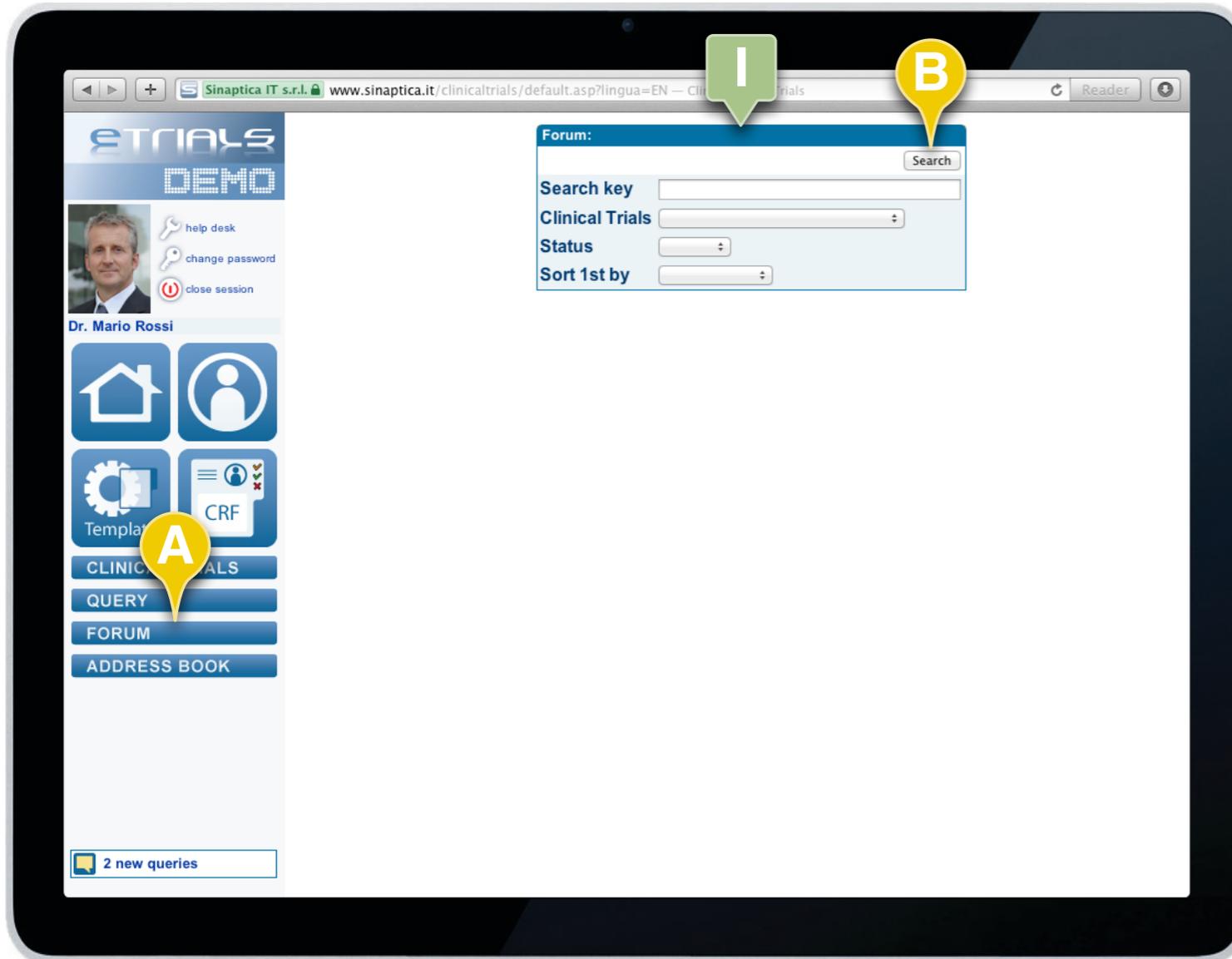
- Form: selecting the Planner button you can visualize the study Planner.
- Code: clinical trial code.
- Clinical Trial: study name.
- Start date: date in which the study opened.
- End date: date in which the study closed.

 The Investigator can only see general information regarding clinical trials to which he/she has not been associated.

END OF SUBJECT ■

CHAPTER 8

FORUM



8.1 How to search a Forum

To search a forum you need to press the *Forum* button (**A**) in the navigation area. This allows to visualize the appropriate pane (**I**) where you may search a forum according to the following filters:

- Search key: using a word which may have been used in the forum.
- Clinical Trial: a list from where you may select one study to which you are authorized.
- Status: open or closed, related to the forum.
- Order 1st by: it is possible to order results by title, date of opening or closure.

Once the filters have been selected, you need to select the *Search* function button (**B**).

CONTINUES ►

i It is also possible not to use any search filter; this way all forum results to which the Investigator is authorized will be displayed.

Forum: Search

Search key

Clinical Trials

Status

Sort 1st by

Search

Results: 1

	Topic	Date	Post
Open	Study protocol (eTrials DEMO Phase I)	20/9/2013 14:55 20/9/2013 14:57 Bianchi Dr.ssa Emanuela	1 last post:20/9/2013 14:55 (Bianchi Dr.ssa Emanuela)

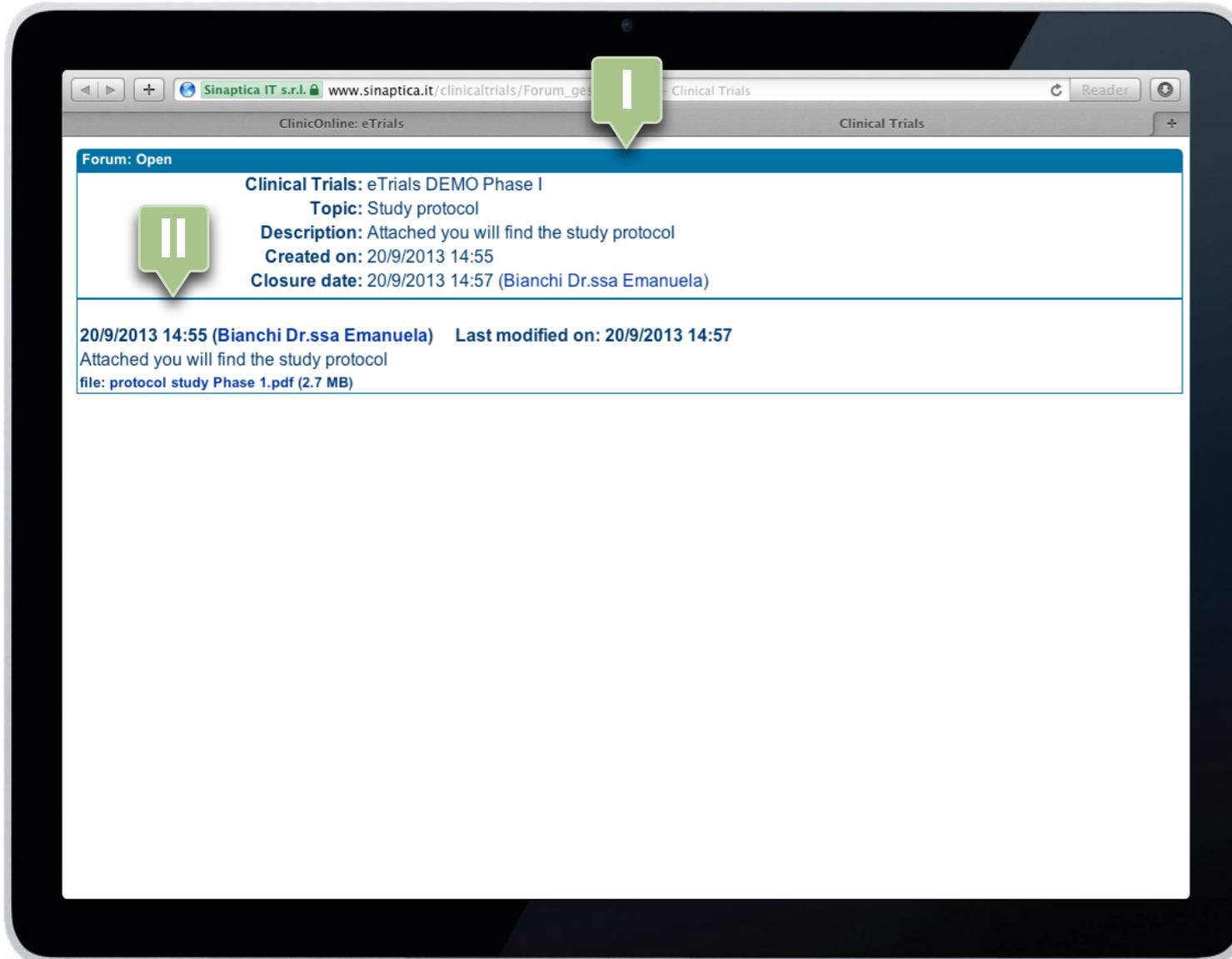
2 new queries

Once the *Search* function button has been selected in the previous window, the system will display the results in the Results pane (I).

The system reports the following forum information:

- In the first column it is present the *Open* function button that allows you to open the form.
- In the second *Forum* column it is present the topic, the clinical trial to which it refers and eventually, any present attachments.
- In the third column, *Date*, you can see the date of opening and closure and the name of the operator who has started the post.
- In the last column, *Post*, the number of contributions and the last operator to enter one with the related data are displayed.

CONTINUES ►



To visualize the forum, once the search was done, you simply need to select the *Open* function button in the appropriate forum.

In the first part of the Forum: Open window (I), the following information are displayed:

- Clinical Trial: the name of the study to which the topic refers.
- Title: title of the forum.
- Text: description by the operator who started the topic.
- Creation date: date and time in which it was created.
- Closure date: if the forum was closed, it is still present and it states the date and time when this operation was done by the operator who did it.

Right after (II) all posts in the forum with their date, time and author are displayed.

END OF SUBJECT ■

 The system also gives the possibility of adding new contributions by the Investigator. This operation needs to be explicitly authorized.

CHAPTER 9

ADDRESS BOOK



9.1 How to search Contact Details

To search within the Address Book you simply need to click the *Address Book* (A) button in the navigation area.

The system automatically searches all users that are linked to the same group of the Investigator.

In the pane Address Book: Search (I) it is possible to use the following filters:

- User: fill in the name of the user you want to search.
- Clinical Trial: you may search for users associated to a particular study.

In the Results pane (II) the users corresponding to the filters are displayed.

For each operator the following information are displayed:

- Family name, title (if present), and name of the operator.
- Operator's image.
- Telephone number.
- Mobile phone number.
- E-mail address.
- Skype contact.

i When the Address Book button is selected (A), the system automatically searches all operators that are associated to the same group the Investigator is.

END OF SUBJECT ■



SINAPTICA IT srl

20 Collalto Sabino str., 00199, Roma, Italy

phone +39.06.8606910

skype sinaptica.it

email info@sinaptica.it

website www.sinaptica.it

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are recorded by Sinaptica IT in Italy.