ORTA

Site Training

Version 1.0

27 Nov 2023

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What is ORTA?

- <u>O</u>n-line <u>R</u>andomized <u>T</u>rials <u>A</u>ccess

- Web-based application for registration and randomization of patients into EORTC clinical trials

- Control & monitor patient enrollment

- Go to the <u>ORTA documentation website</u> for more information on the system requirements and to download user guide.
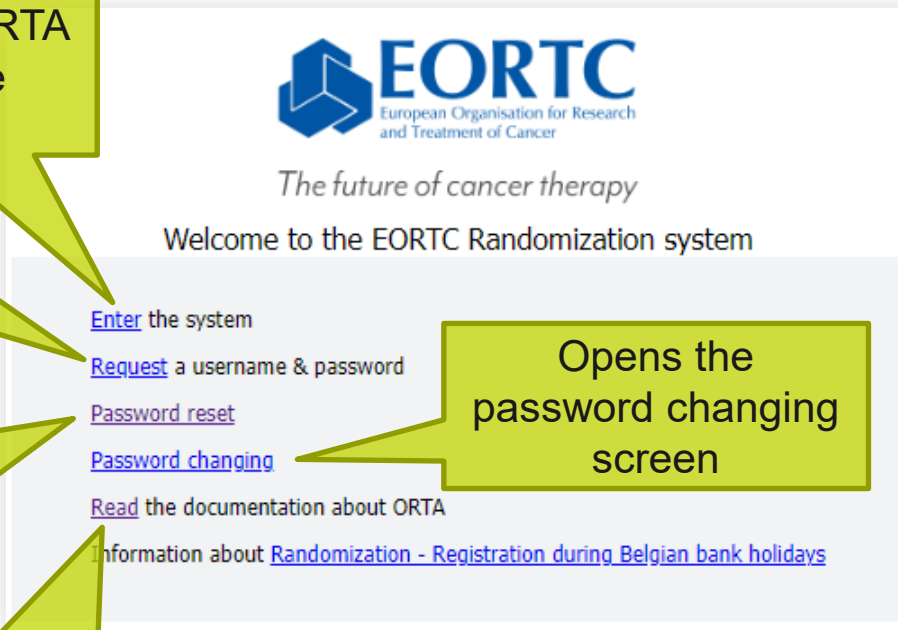
How to login? (1)

Opens the ORTA login page

Opens the EORTC account request form
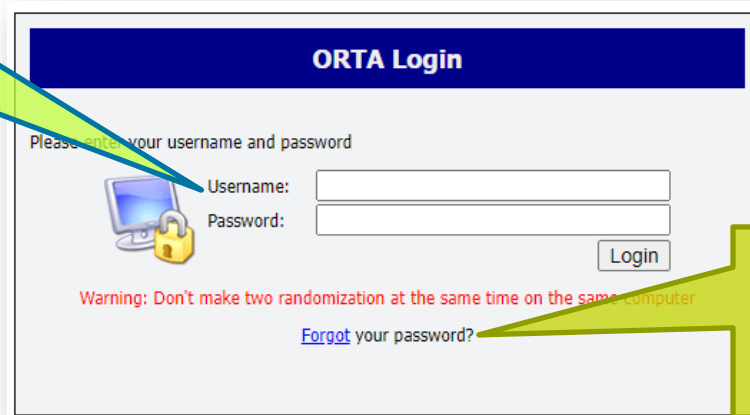
Opens the account reminder form to reset your password

The future of cancer therapy

Welcome to the EORTC Randomization system

Enter the system

Request a username & password

Password reset

Password changing

Read the documentation about ORTA

Information about Randomization - Registration during Belgian bank holidays

Opens the password changing screen

Opens the ORTA documentation website for additional information

How to login? (2)

Enter your ORTA* user name and password**

ORTA Login

Please enter your username and password

Username:

Password:

Login

Warning: Don't make two randomization at the same time on the same computer

Forgot your password?

An automatic e-mail will be sent to you allowing you to **reset** your password

*On-line Randomized Trials Access (**ORTA**) credentials are sent as automatic e-mail message from Randlog@eortc.org to your inbox (or spam folder).

First time login will prompt you to **immediately change your password; afterwards, you are asked to update **every 3 months**. Do **not** use accents in your password.

How navigate in ORTA? (1)

Enter EORTC institution number

Click on 'Details'to open the EORTC clinical trial page with trial details after entry of the protocol number
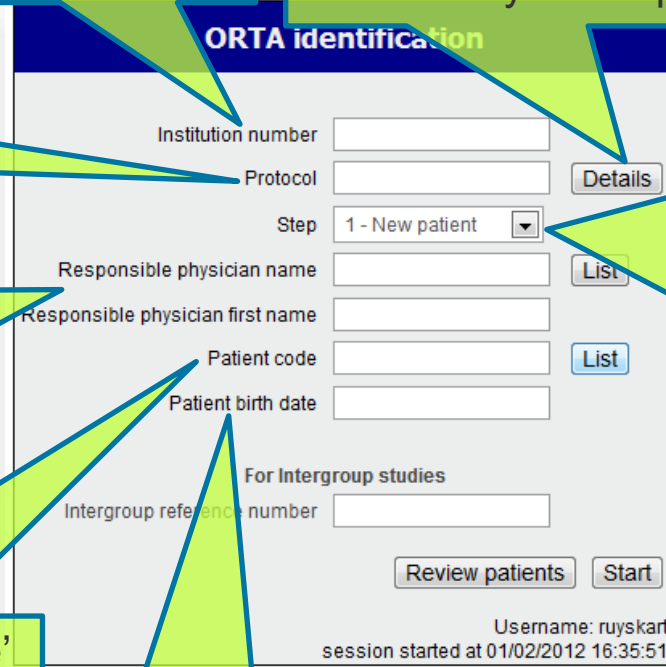
Enter EORTC protocol number (i.e., 4 or 5 digits)

The dropdown list 'Step' allows you to register a new subject ('1 – New patient'), continue next steps with registered subjects ('x – Existing patient') or blinded treatment allocation of registered subjects ('Resupply treat.') according to the protocol setting

Enter the 'name' and 'first name' of the responsible physician or select the responsible physician from the 'List'

ORTA identification

Institution number

Protocol [Details]

Step [1 - New patient ▼]

Responsible physician name [List]

Responsible physician first name

Patient code [List]
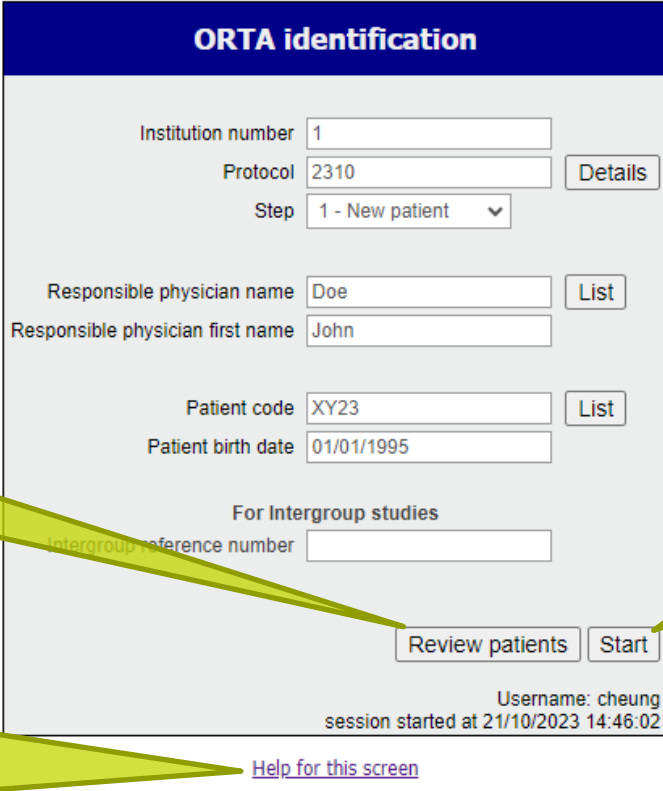
Patient birth date

For Intergroup studies

Intergroup reference number

[Review patients] [Start]

Username: ruyskart
session started at 01/02/2012 16:35:51

Enter an unique 'Patient code' or select the existing subject from the 'List':
• Alphanumeric (Max. 4 characters)
• Cannot start with a numeric value
• No initials

Enter the 'Patient birth date' in DD/MM/YYYY format.

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How navigate in ORTA? (2)

ORTA identification

Institution number	1
Protocol	2310 [Details]
Step	1 - New patient
Responsible physician name	Doe [List]
Responsible physician first name	John
Patient code	XY23 [List]
Patient birth date	01/01/1995

For Intergroup studies
Intergroup reference number

[Review patients] [Start]

Username: cheung
session started at 21/10/2023 14:46:02

Help for this screen
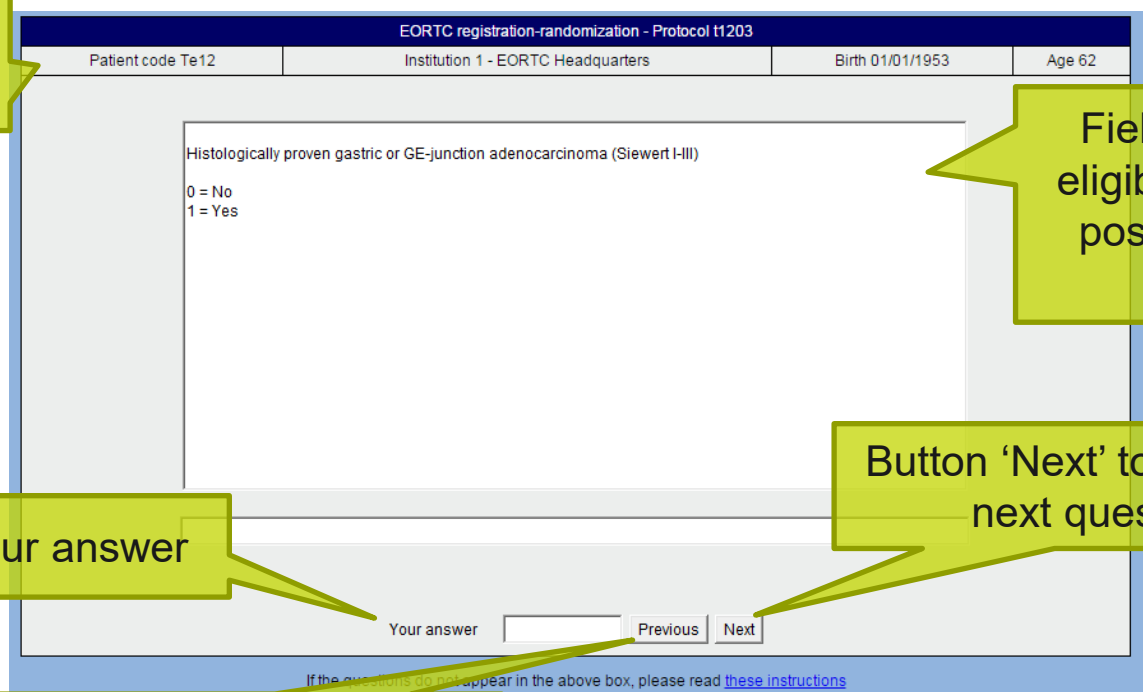
Opens an overview of the enrolled subjects.

The 'Start' button will initiate the eligibility criteria check after correct completion of the ORTA identification

Opens the 'Identification screen help page' to guide the completion of the ORTA identification step

Important note: Only institutions that have officially been authorized by EORTC for the study protocol are allowed to enter new subjects and complete subsequent steps in ORTA.

How navigate in ORTA? (3)

Patient and institution identification

Field containing the eligibility question and possible answers, if applicable

Button 'Next' to go to the next question

Field to enter your answer

Button 'Previous' to return to the previous question

EORTC registration-randomization - Protocol t1203			
Patient code Te12	Institution 1 - EORTC Headquarters	Birth 01/01/1953	Age 62

Histologically proven gastric or GE-junction adenocarcinoma (Siewert I-III)

0 = No
1 = Yes

Your answer [ ] Previous Next

If the questions do not appear in the above box, please read these instructions

Instructions: Correct completion of the eligibility check will result in the allocation of a patient number (i.e., SeqID), which is used throughout the study and systems. In case of mistakes, you will not be able to advance to the next question.

Contact

- Refer to study protocol for study-specific instructions related to the eligibility criteria and steps.

- Contact the EORTC study team for your study-specific and technical questions related to ORTA.