

# ORTA web user guide

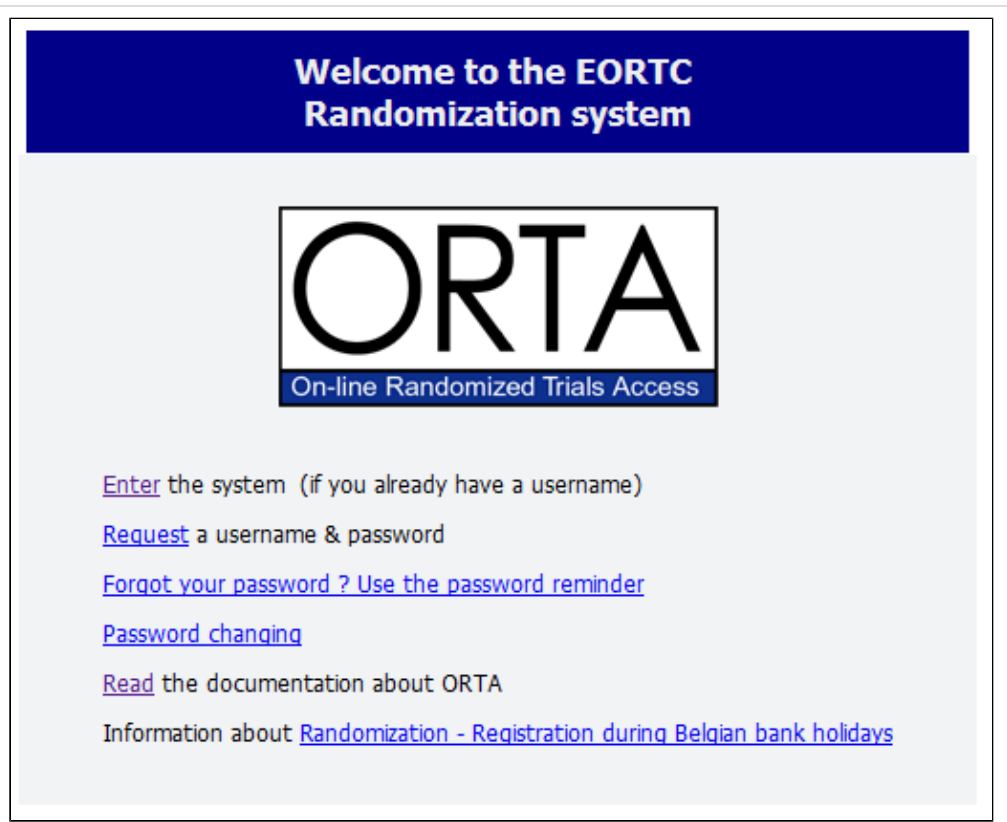
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## Overview

ORTA is a web-based application designed to facilitate the registration & randomization of patients in EORTC clinical trials.

Registration/Randomization is the process whereby a patient is entered into an EORTC study. The Registration/Randomization process checks the investigator's authorization to include patients in the study, then checks the patient's eligibility, and finally assigns the treatment and patient identification number (seqid). Access is controlled through a user name and password, and actual patient registration is controlled through an authorization list.

Registration/Randomization is done in 4 phases. These steps are: logon, identification, eligibility checking, and treatment (and seqid) allocation.



**Welcome to the EORTC  
Randomization system**

**ORTA**  
On-line Randomized Trials Access

[Enter](#) the system (if you already have a username)

[Request](#) a username & password

[Forgot your password ? Use the password reminder](#)

[Password changing](#)

[Read](#) the documentation about ORTA

Information about [Randomization - Registration during Belgian bank holidays](#)

## Accessing ORTA

The web address of ORTA is <http://orta.eortc.be/>

## System requirements

ORTA is available from any web browser with JavaScript enabled, which is the case for all browsers by default.

You can check your browser configuration on <http://orta.eortc.be/doc/default.htm>, in the System Requirements section.

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## Username and password

To enter the system you need to have a username and a password. You can request a username on-line by filling the form available from the ORTA main page. Your username and password will be sent to you by e-mail.

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## Login to ORTA

Once you receive the confirmation of your account by e-mail you can enter the system.



**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?](#)

Identify yourself by entering your username and your password. Click on LOGIN.

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## Passwords

The password that you receive is a temporary password, the first time you use it, you will be prompted to choose another password. Choose whatever password you like, but with at least 6 characters. A combination of alphanumeric characters is preferable. Passwords expire after 3 months. You do not need to connect every 3 months to change your password. When you connect with an expired password, the system will ask you to choose a new one.

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## Registration/Randomization

Once logged on, you can begin the actual Registration/Randomization process. The first step is to identify yourself and your patient.

## Patient Identification screen

The identification screen prompts you to enter your details, as well as the study, protocol, and patient details. Certain fields allow you to check the validity of the information by displaying a list of acceptable choices. Access beyond this point is only allowed for studies for which you have fulfilled the necessary requirements for participation.

ORTA identification

Institution number

Protocol  Details

Step  ▼

Responsible physician name  List

Responsible physician first name

Patient code  List

Patient birth date

**For Intergroup studies**

Intergroup reference number

Username: dienne  
 session started at 19/08/2016 14:46:40

[Help for this screen](#)

	Description of the fields in the patient identification screen
<b>Institution number</b>	EORTC Institution number
<b>Protocol</b>	Protocol number
<b>Step</b>	1 for a new patient; 2, 3, 4 or 5 for multi-steps studies; or "Resupply" for getting a treatment resupply in a double-blind study.
<b>Responsible physician name and first name</b>	Correct spelling will be checked with our address database; in case of misspelling a list will be displayed for selection, with all official members in your center or click on "List Phys." To select from a list of names. Click one name to select it. Please select the principal investigator name for the study (= the name on the "Commitment Statement/Study Acknowledgement" form of the study).
<b>Patient code</b>	Max. 4 alpha –numeric characters (click "LIST" to select your patient in step 2, 3, 4 or 5)
<b>Patient birth date</b>	Patient birth date. REMEMBER 4 digits for the year, "/" as separation in day-month-year format
<b>Intergroup reference number</b>	Intergroup patient identification (optional)

When all details are entered, click on "Start" and, if your institution has the authorization, if you have the right to randomize for this institution and if the data you entered is correct, the eligibility checks will start.

## Eligibility checking

The eligibility-checking screen comes after the identification screen.

EORTC registration-randomization - Protocol TPRU

Institution 1 - EORTC Headquarters

Patient code : DABO      Date Of Birth : 24/04/1939      Age : 77

Time of relapse

1 = Less than 16 weeks after the first day of the last TMZ cycle  
2 = 16 or more weeks after the first day of the last TMZ cycle

2

Back      Continue

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Answer all questions as requested in the central window. Activate the cursor in the "Your answer" box by clicking here with your mouse. Click "next" to continue to the next question. Click "previous" to go back to the previous question. Pressing "Enter" has the same effect as clicking "next". Click "back" on the browser toolbar to go to the identification screen.

## Registration/Treatment allocation screen

This screen appears after you have answered all eligibility questions. It displays the sequence number (seqid) of your patient and the treatment allocated.

Warning: the question numbers here are not the same as on the randomization forms. Some extra questions (hidden) are usually added for cross checks and eligibility checking calculations.

Please write the patient sequence number (seqid) and the treatment allocated on the eligibility checklist.

If, for any reason, you can't see this screen, please call the EORTC Headquarters for help (+32 2 774 16 00) or go back to the identification screen.

## Utilities for reviewing patient details

From the main identification screen, you can enter a protocol number, an institution number and by pressing the "Review patients" button you will be able to check the information you entered for your patients. After pressing the "Review patients" button you will see the list of patients.

## Protocol: TEST

Click on the patient code to see the answers to the questions.

Click on the square near the patients code to see the answers & the questions.

Code	Seqid	Step	Protocol	Chart	Inst.	Birthdate	Registration date
<input type="checkbox"/> <a href="#">defq</a>	9	2	TPRU		1	04/04/1944	04/08/2016 10:21:49
<input type="checkbox"/> <a href="#">ixch</a>	34	1	TPRU		1	01/01/1915	04/08/2016 10:20:03
<input type="checkbox"/> <a href="#">duiz</a>	33	1	TPRU		1	01/01/1925	04/08/2016 10:07:53
<input type="checkbox"/> <a href="#">12rg</a>	32	1	TPRU		1	12/12/1954	03/08/2016 13:27:45
<input type="checkbox"/> <a href="#">reeq</a>	31	1	TPRU		1	15/02/1789	02/08/2016 13:42:32
<input type="checkbox"/> <a href="#">ree</a>	30	1	TPRU		1	30/01/1841	02/08/2016 13:39:43
<input type="checkbox"/> <a href="#">AD92</a>	29	1	TPRU		1	14/02/1992	22/07/2016 10:53:55
<input type="checkbox"/> <a href="#">bqhy</a>	28	1	TPRU		1	01/01/1956	01/06/2016 16:36:15
<input type="checkbox"/> <a href="#">GTHY</a>	27	1	TPRU		1	02/02/1922	01/06/2016 15:28:50
<input type="checkbox"/> <a href="#">AAA5</a>	5	2	TPRU		1	01/01/1972	15/02/2016 17:14:31
<input type="checkbox"/> <a href="#">AAA1</a>	1	2	TPRU		1	01/01/1988	02/02/2016 09:09:50
<input type="checkbox"/> <a href="#">DEFR</a>	26	1	TPRU		1	08/08/1965	21/01/2016 11:00:13
<input type="checkbox"/> <a href="#">DEFR</a>	25	1	TPRU		1	08/08/1955	21/01/2016 10:57:45
<input type="checkbox"/> <a href="#">qgth</a>	24	1	TPRU		1	02/02/1955	21/12/2015 14:33:39

By clicking on the code, you get the registration/randomization information (checklist, birth date ...) for each patient.

**Study:** TPRU - **Institution:** 1

**Step:** 1 - **Seq.id:** 29

**Code:** AD92 - **Chart:** - **Birth Date:** 14/02/1992

**Question 1:** 1 (24)

**Question 2:** 0 (0)

**Question 3:** 1 (25/10/2015)

**Question 4:** 1 (1)

**Treatment:** 1

Treatment description: Arm 1A - Lomustine 110mg/m<sup>2</sup> on day 1 of every 42-day treatment period.

Treatment will continue until one of the treatment withdrawal criteria has been met.

Lomustine will be given for a maximum of one

Treatment Instructions: Instructions for code 1

**Physician:** Ruyskart Pascal

**Group1:**

**Group2:**

**Login:** Ruyskart (Pascal Ruyskart)

**Host:** 10.1.200.187

**Date:** 22/07/2016 10:53:55

By clicking on the small square before the patient's code on the Patient Review web page, you get the registration/randomization information and the phrasing for each question.

**Study:** TPRU - **Institution:** 1

**Step:** 1 - **Seq.id:** 29

**Code:** AD92 - **Chart:** - **Birth Date:** 14/02/1992

Quest.	Description	Val.	Code
1	F:AGE	24	1
2	WHO Performanse Status (0 - 4)	0	0
3	Date of signature of written informed consent for the registration procedure (dd/mm/yyyy)	25/10/2015	1
4	Time of relapse 1 = Less than 16 weeks after the first day of the last TMZ cycle 2 = 16 or more weeks after the first day of the last TMZ cycle	1	1

## Tools to contact ORTA Support

In case of problem during the eligibility checking, an expected behavior, a bug in the navigation through questions, etc.

You have the possibility to contact ORTA Support and provide them some useful information to help you.


**EORTC registration-randomization - Protocol TADI**

**Institution 1 - EORTC Headquarters**


Patient code: **AYDI**      Date Of Birth: **14/02/1986**      Age: **30**

Date of signature of written informed consent for central EGFR screening according to ICH/GCP and applicable national laws (dd/mm/yyyy)

Please note to enter the date in the proper format (DD/MM/YYYY)

dd/mm/yyyy 

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Click on the version number on the bottom right corner.

On the new window :

**ORTA Session information**
✕

**General Informations**

You are connected as : **dienne**      Registration of : **AYDI - 1986/02/14**  
Protocol : **TADI**      Institution : **1**      Responsible Physician : **Pascal Ruyskart**  
Agent : **Mozilla/5.0 (Windows NT 6.1; WOW64; rv:50.0) Gecko/20100101 Firefox/50.0**

**How contact IT Support ?**

**Step 1** - Send a report of this process : Send the report

**Step 2** - Send an email to the [IT support for ORTA](#) ✉

Ok

You can contact ORTA support in 2 steps only :

1. Click on 'Send the report' button to help investigation by the support team.
2. Click on the link to have a pre-formatted email.  
You can edit it to provide your feedback and send it.

## Treatment resupply for blind studies

In case of blind study, the identification screen provides a way to get a treatment resupply for a patient.

ORTA identification

Institution number

Protocol  Details

Step  List

Responsible physician name  List

Responsible physician first name

Patient code  List

Patient birth date  List

Patient birth date

**For Intergroup studies**

Intergroup reference number

Review patients
Start

Username: ruyskart  
session started at 02/10/2012 10:51:02

This is done by selecting 'R' as the step of the patient. Once all the fields are completed and the patient selected the start button will lead to the following confirmation screen. At this stage, you can review the information, and if correct proceed to the treatment renewal with the "get treatment link".

## Treatment renewal

Protocol number: TPRU

Sequential number: 5

Instit: 1

Chart:

Birth: 5/1/1981

Initials: AE

Please check the information above and confirm you want a treatment renewal for this patient by following the link here under

[Get treatment renewal for patient seqid 5](#)

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## Online unblinding for blind studies

Some studies are setup with an online unblinding feature allowing the physician to reveal the treatment code of a patient enrolled a blind study.

### **Warning**

The circumstances in which on-line unblinding can be performed are strict and defined in the protocol.

The number of the unblinding step is defined in the study documentation. Once this step is selected a list of questions are presented in order to check the legibility of the unblinding. At the end of the process, if answers are satisfactory and confirmed the treatment is displayed.

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## Support

For further information and support, please see the FAQ (Frequently asked questions) section on the ORTA website or contact [orta@eortc.be](mailto:orta@eortc.be)