TOP patient registration
1. Table of contents

1. Table of contents .............................................................................................................. 2
2. Prerequisites .................................................................................................................. 2
3. Getting started ................................................................................................................ 2
4. Registration/randomization of a new patient ................................................................. 3
5. Registration/randomization of an existing patient ......................................................... 7
6. Reviewing existing patients ........................................................................................ 10
7. Troubleshooting ............................................................................................................ 12

2. Prerequisites
To be able to use TOP you will need to have:

- Microsoft Internet Explorer version 4 or higher installed on your pc;
- a connection to the internet;
- the TOP security certificate installed on your pc, for details see the HOVON website (www.hovon.nl studies documents TOP information and documents);
- a username and password for TOP, if you do not have a username and password fill out a “TOP IKW logon application form” (http://www.clinicalresearch.nl/portec3) and send it to the IKW Trial office. For confirmation you will receive two e-mails from TOP, one with your username and one with your password.

3. Getting started

- Go to the TOP website at https://www.admlumc.hovon.nl
- Fill out your username and password and click [Login].
- You will be in the main menu in TOP (contents depends on the rights you have in TOP).
4. Registration/randomization of a new patient

- From the main menu click **Patient registration/randomization**.

- Select the relevant study from the drop down menu. You will only be able to select a study for which your organization or an affiliated organization can register patients.

- For a new patient click the New patient button ( ), if necessary, and click the [Next] button.
In the next screen fill out the general patient data and click the [Next] button. You can use the Tab key to switch between items. The following items are available:

- **Registering person or caller:** this is the person who actually registers the patient, this can be the name of the treating physician, research nurse, local datamanager, etc.;

- **Patient name code:** use a three-letter code, preferably the first letter of the patient’s first name and the first two letters of his/her last name. If the patient is a married woman, use the first letter of her first name and the first two letters of her maiden name;

- **Hospital record no.:** this is the number by which the patient is known in his/her hospital. This is an optional item that may be left blank, if this item is filled out it will be easier for other persons with a function within the study (for instance a pathologist, cytogeneticist, local datamanager, etc.) to identify the patient;

- **Hospital:** from the drop down menu select the hospital in which the patient will receive his/her protocol treatment. The drop down menu will be restricted to the hospital(s) for which you have rights to register patients;

- **Responsible physician:** select the physician that will be responsible for protocol treatment for this patient from the drop down menu, if the responsible physician is not available in the drop down menu fill out his/her name in the open field in front of the drop down menu;

- **Date of birth:** fill out the patient’s date of birth as dd/mm/yyyy (day, month, year);

- **Sex:** select the patient’s sex from the drop down menu;

- **Comments:** this is an optional item that may be left blank.
TOP will now check if a patient with similar sex and date of birth has already been registered in the study to avoid accidental double registrations. If a matching patient was found only continue if you are absolutely certain the patient has not been registered yet by following the instructions on screen. If no matching patients were found continue by clicking the [Continue registration] button.

On the next screen fill out all questions truthfully. The questions on this screen are the same as on the corresponding case report forms. Most questions are multiple choice and can be answered by selecting an answer from the drop down menu. Fill out dates as dd/mm/yyyy (day, month, year). Lab values should be filled out without unit and with a dot as decimal sign. Leaving questions blank is not allowed unless stated otherwise.
If you realize you have made a mistake in the general patient data you can go back by clicking the **Patient data** option on the left of your screen. In this case you will lose any answers already filled out on the present screen.

After filling out all answers click [Enter data]. TOP will now check eligibility of the patient based on the answers given. In case of ineligibility TOP will give a warning and the involved answer will be marked with a red bar. Check the answer and correct if necessary. If the answer that was filled out is correct the patient is not eligible.

If the patient is eligible TOP will register the patient, send confirmation e-mails and randomize the patient, if applicable. At this point you can no longer make corrections in any answer given (including
general patient data). After registration TOP will return a screen reporting the allocated patient number, all answers given and randomization result if applicable. You can print a report by clicking the [Print] button at the bottom of this screen.

- Registration is finished and you can now safely close Internet Explorer to end your session in TOP.

5. **Registration/randomization of an existing patient**

- To perform a late/second registration or randomization for an already existing patient in TOP click **Patient registration/randomization** in the main menu.

- Select the relevant study from the drop down menu, you will only be able to select a study for which your organization or an affiliated organization can register patients.

- Click the Select a patient button ( ), select the relevant patient from the drop down menu and click the [Next] button.
• TOP will display the general patient data and a summary of the forms already filled out in TOP.

• Select the relevant empty form on the left side of your screen.

• On the next screen fill out all questions. Most questions are multiple choice and can be answered by selecting an answer from the drop down menu. Fill out dates as dd/mm/yyyy (day, month, year). Lab values should be filled out without unit and with a dot as decimal sign.
• After filling out all answers click [Enter data]. TOP will now check eligibility of the patient based on the answers given. In case of ineligibility TOP will give a warning and the involved answer will be marked with a red bar. Check the answer and correct if necessary. If the answer that was filled out is correct the patient is not eligible.

• If the patient is eligible TOP will register this form for the patient, send confirmation e-mails and randomize the patient if applicable. At this point you can no longer make corrections in any answer given. After registration TOP will return a screen reporting all answers given and randomization result if applicable. You can print a report by clicking the [Print] button at the bottom of this screen.
• Registration/randomization is finished and you can now safely close Internet Explorer to end your session in TOP.

6. Reviewing existing patients

• To review general patient data or answers filled out on any form for an existing patient click Patient registration/randomization in the main menu.

• Select the relevant study from the drop down menu, you will only be able to select a study for which your organization or an affiliated organization can register patients.

• Click the Select a patient button, select the relevant patient from the drop down menu and click the [Next] button.
• TOP will display the general patient data and a summary of the forms already filled out in TOP.

• To review the answers given in a specific form click the relevant form on the left side of your screen.
7. Troubleshooting

- At any time prior to the actual registration in TOP (i.e. acceptance of the patient by TOP and allocation of patient study number and randomization result) you can cancel the procedure by closing Internet Explorer.

- If you have trouble entering TOP check the following:
  - Ensure that the URL you typed is https://www.admlumc.hovon.nl
  - Ensure that the TOP security certificate is installed on your pc by going to Tools → Internet Options…. In the next window go to the Content tab and click [Certificates…]. In the next window go to the Intermediate Certification Authorities tab and check whether or not an entry is present for www.admlumc.hovon.nl. If not, follow instructions about the security certificate on the HOVON website (www.hovon.nl → studies → documents → TOP information and documents).
  - Ensure that the page you see is not an old version of TOP still present in the cache of Internet Explorer by going to Tools → Internet Options…. In the next window click [Delete Files…] and try accessing TOP again. To ensure that this does not occur again go to Tools → Internet Options…. In the next window click [Settings…]. In the next window ensure that Never and Automatically are not selected.
  - If you have any questions or problems while using TOP you can contact the IKW Trial office (tel.: +31(0)71-5263052; fax: +31(0)71-5266712). In case of technical difficulties, please first check whether or not it is a local problem with your pc or network.