TOP patient registration

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2. Prerequisites

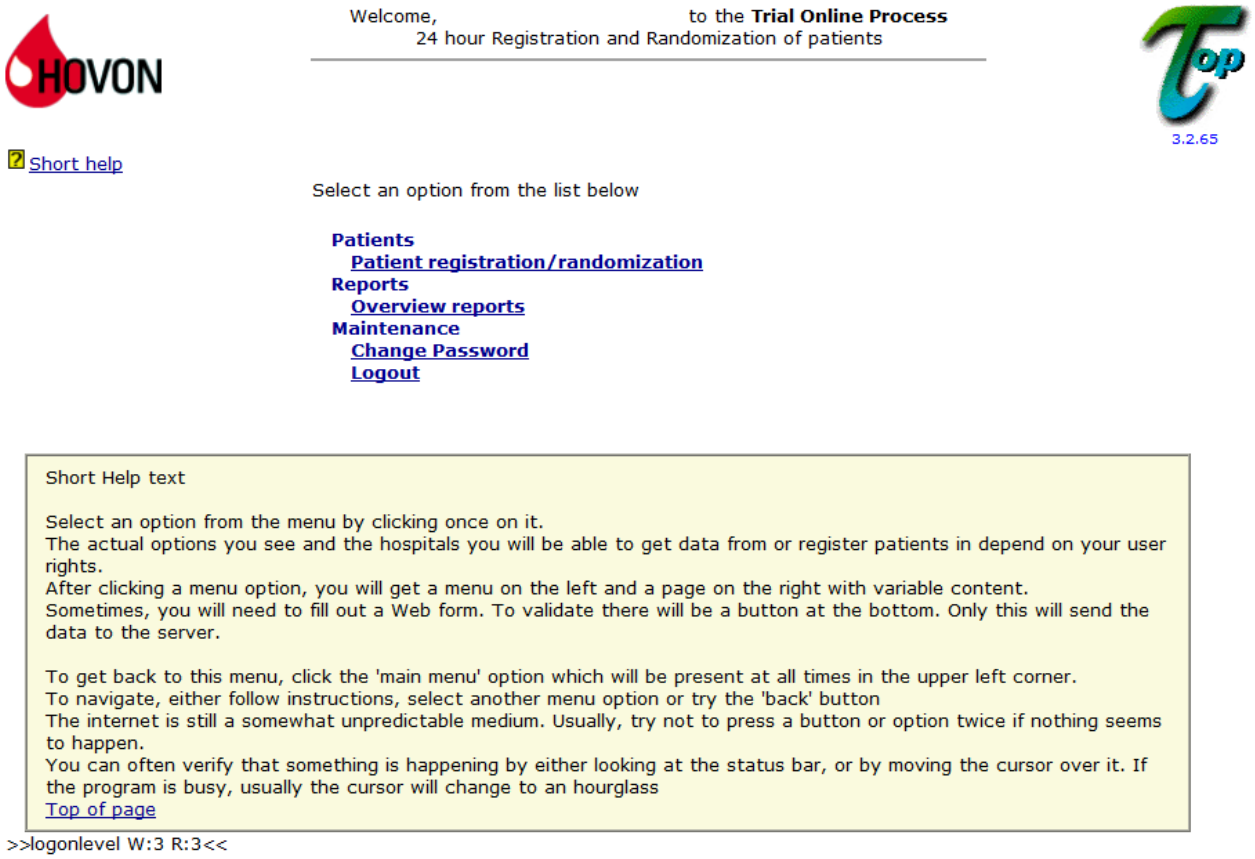
To be able to use TOP you will need to have:

- Microsoft Internet Explorer version 4 or higher installed on your pc;
- a connection to the internet;
- a username and password for TOP, if you do not have a username and password fill out a “TOP logon request form” (www.hovon.nl → studies → documents → TOP information and documents) and send it to the HOVON Data Center. For confirmation you will receive two e-mails from TOP, one with your username and one with your password.

3. Getting started

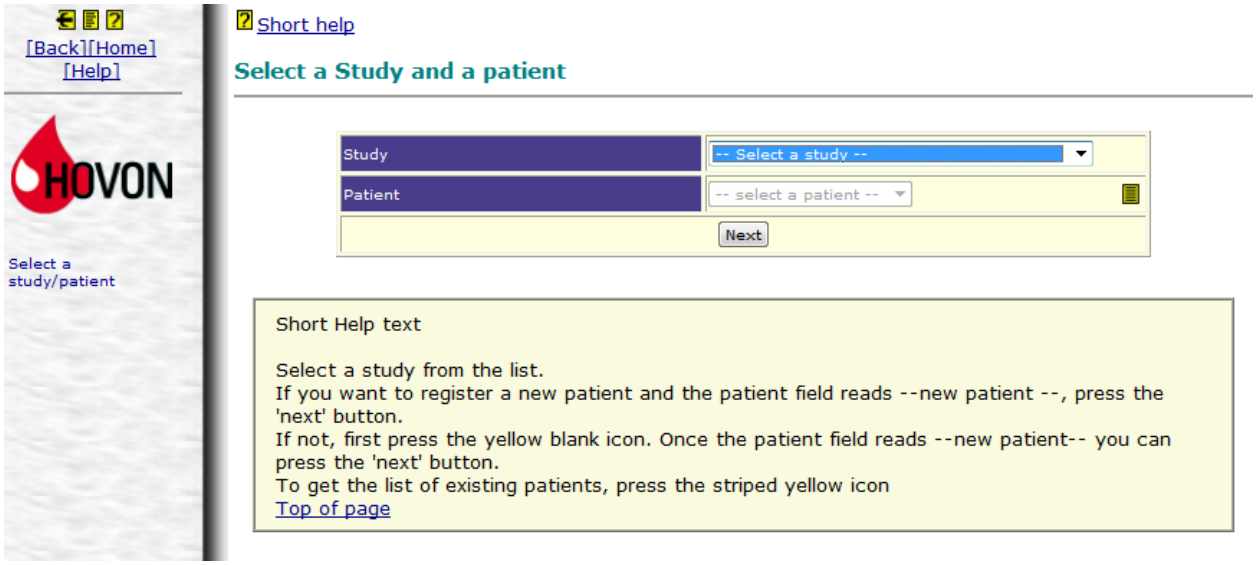
- Go to the TOP website at https://www.hdc.hovon.nl/top .

- 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).

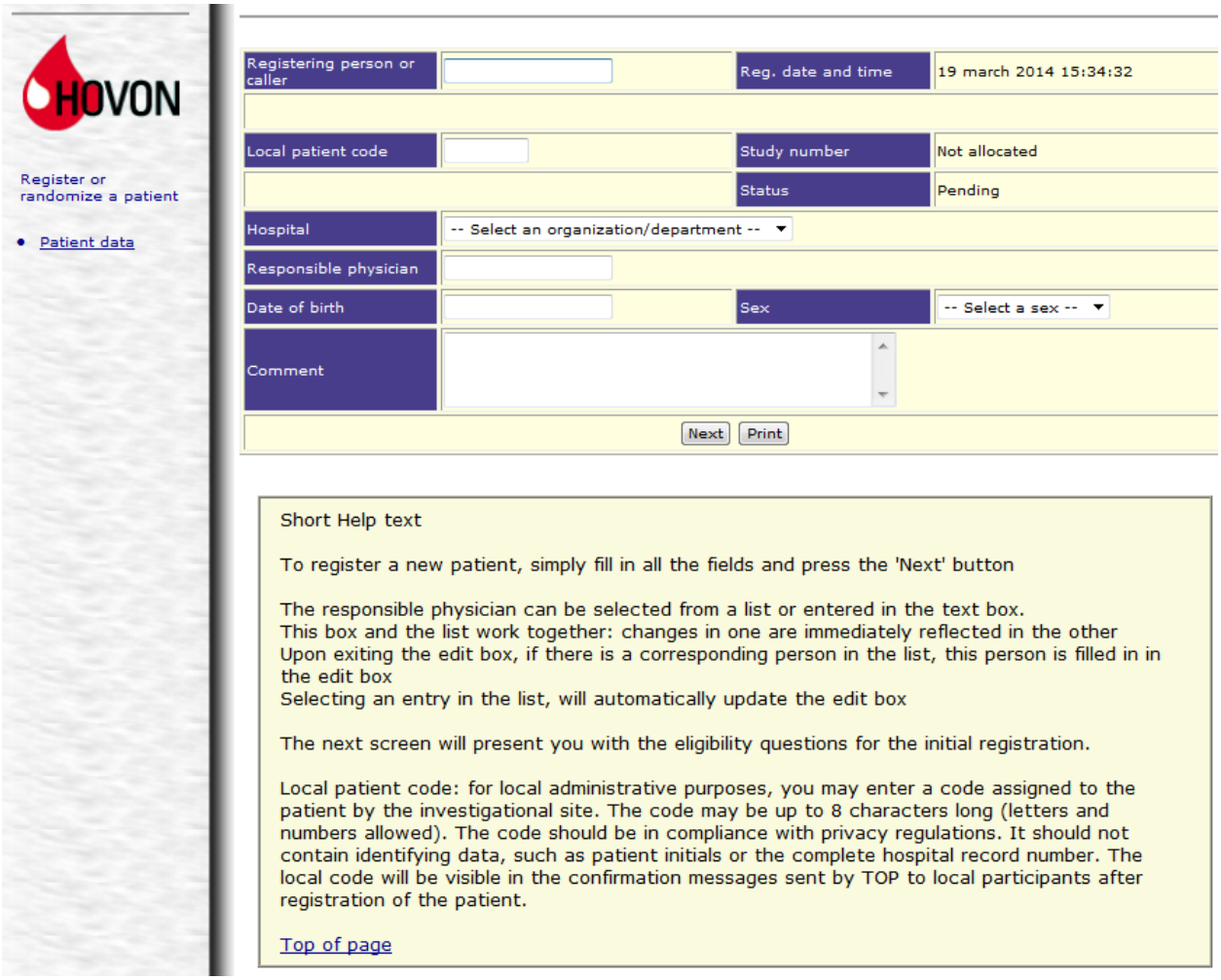


4. Registration/randomization of a new patient

- 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.

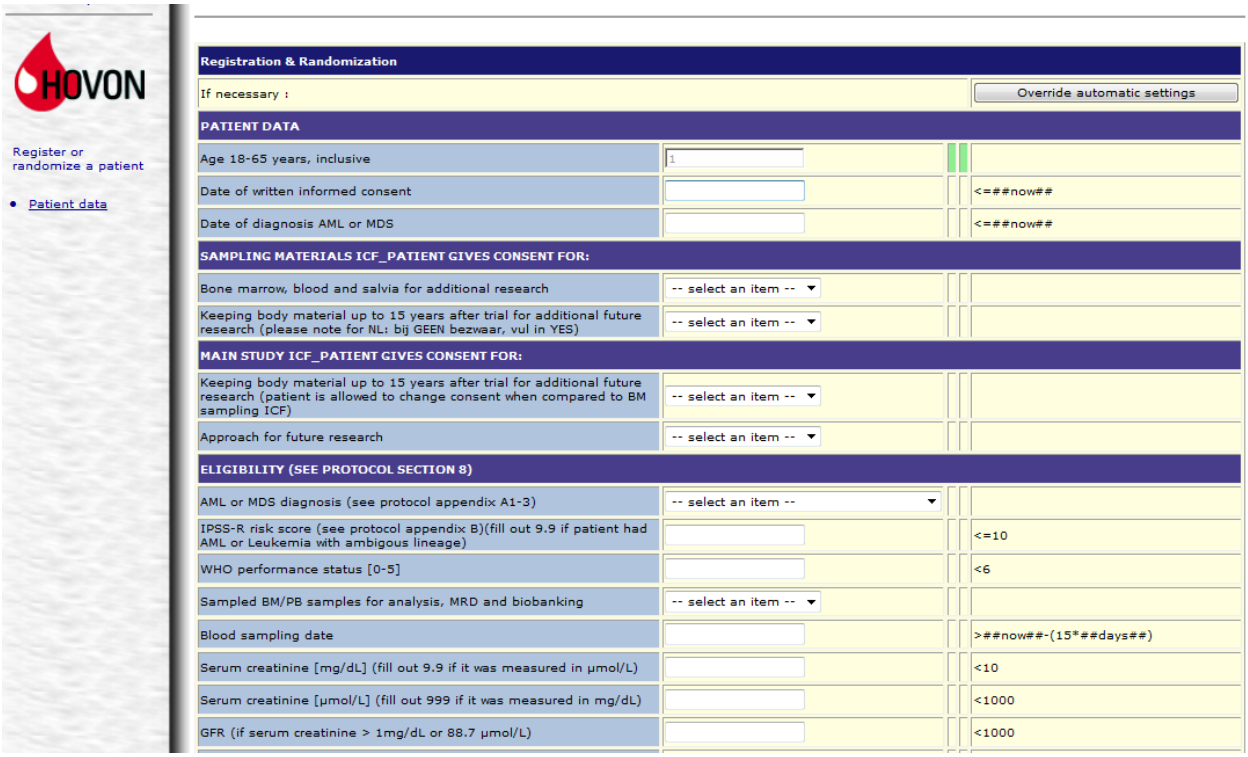


- For a new patient click the New patient button ( ), if necessary, and click the [Next] button.



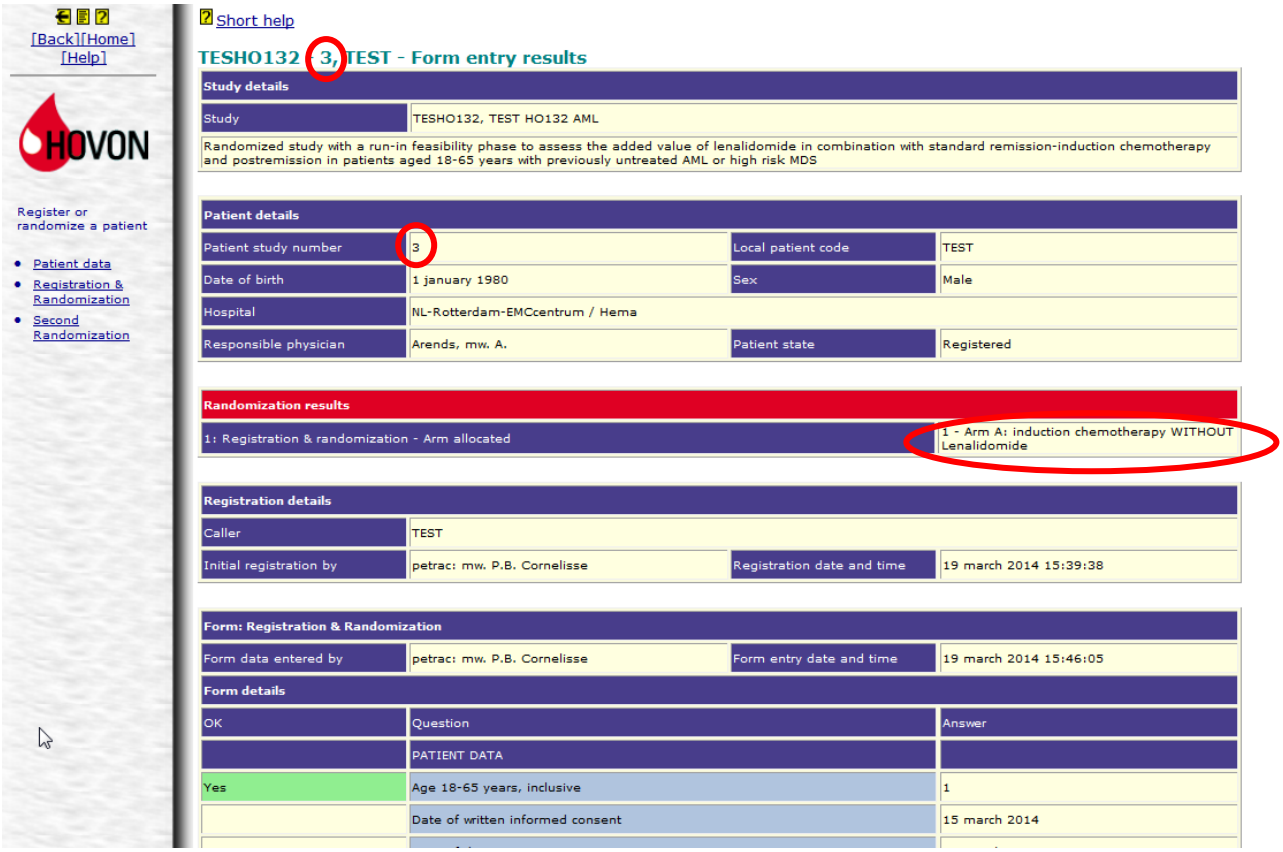
- In the next screen (see above) fill out the general patient data and click the [Next] button. You can use the Tab key to switch between items. The following items are available:
  - Registering person or caller: this is the person who actually registers the patient, this can be the name of the treating physician, research nurse, local datamanager, etc.;
  - Local patient code: this is not obligatory. You can use this for local administrative purposes. The code may be up to 8 characters long (letters and numbers allowed). The code should be in compliance with privacy regulations. It should not contain identifying data, such as patient initials or the complete hospital record number. The local code will be visible in the confirmation messages send by TOP to local participants after registration of 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.
- 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. On the right of the answer boxes, you might find some more details that provide details on boundaries used.



- 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 loose 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.

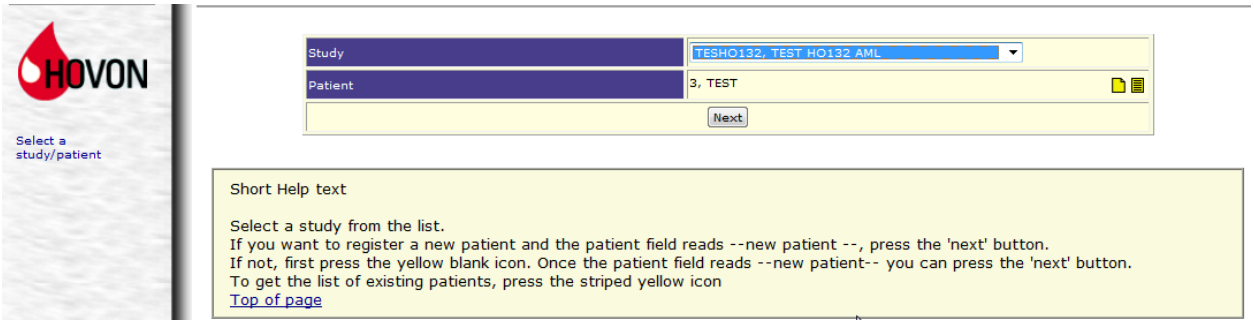
- If the patient is eligible TOP will register the patient, send confirmation e-mails and randomize the patient, if applicable. At this point you can no longer make corrections in any answer given (including general patient data). After registration TOP will return a screen reporting the allocated patient 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.



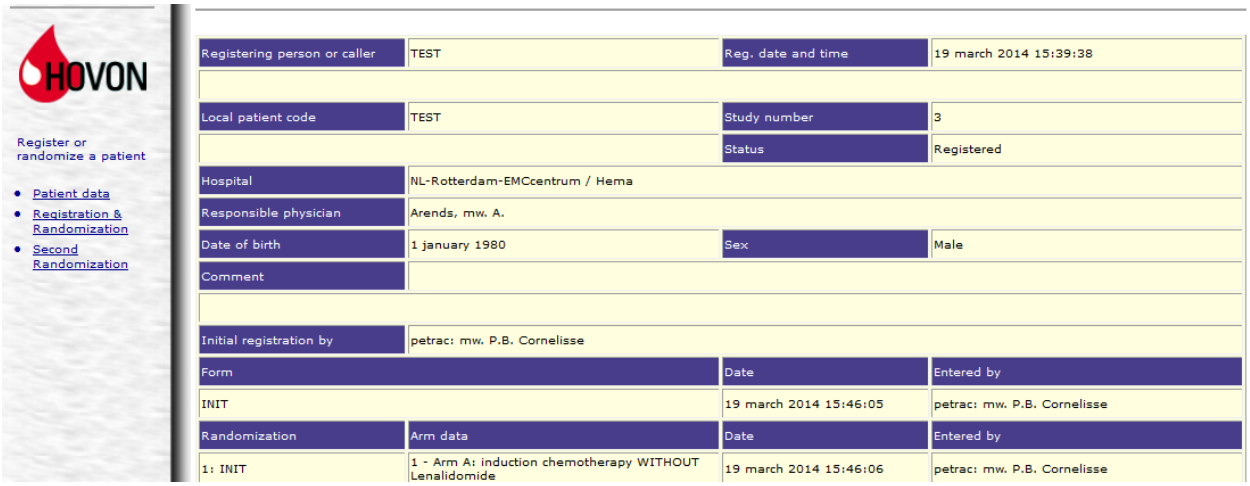
- Registration is finished and you can now safely close log out to end your session in TOP.

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.



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Register or randomize a patient

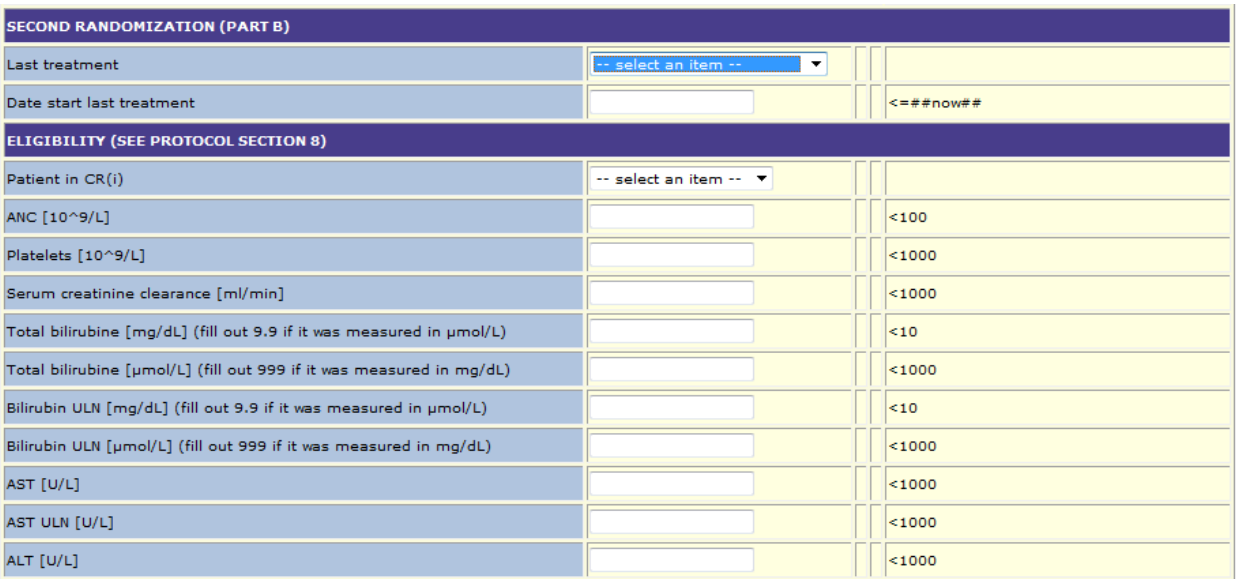
- Patient data
- Registration & Randomization
- Second Randomization

Registering person or caller	TEST	Reg. date and time	19 march 2014 15:39:38
Local patient code	TEST	Study number	3
		Status	Registered
Hospital	NL-Rotterdam-EMCcentrum / Hema		
Responsible physician	Arends, mw. A.		
Date of birth	1 january 1980	Sex	Male
Comment			
Initial registration by	petrac: mw. P.B. Cornelisse		

Form	Date	Entered by
INIT	19 march 2014 15:46:05	petrac: mw. P.B. Cornelisse

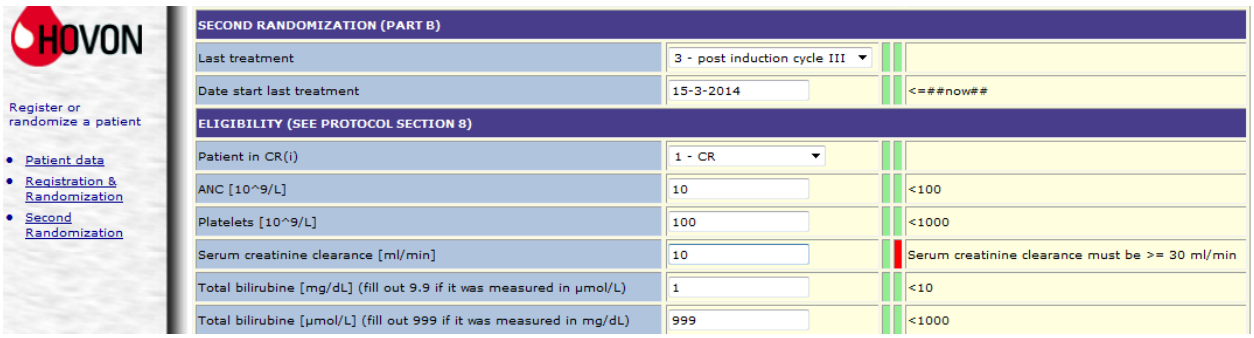
Randomization	Arm data	Date	Entered by
1: INIT	1 - Arm A: induction chemotherapy WITHOUT Lenalidomide	19 march 2014 15:46:06	petrac: mw. P.B. Cornelisse

- Select the relevant empty form on the left side of your screen (e.g. Second Randomization).
- 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.



SECOND RANDOMIZATION (PART B)		
Last treatment	-- select an item --	
Date start last treatment		<=##now##
ELIGIBILITY (SEE PROTOCOL SECTION 8)		
Patient in CR(i)	-- select an item --	
ANC [10^9/L]		<100
Platelets [10^9/L]		<1000
Serum creatinine clearance [ml/min]		<1000
Total bilirubine [mg/dL] (fill out 9.9 if it was measured in µmol/L)		<10
Total bilirubine [µmol/L] (fill out 999 if it was measured in mg/dL)		<1000
Bilirubin ULN [mg/dL] (fill out 9.9 if it was measured in µmol/L)		<10
Bilirubin ULN [µmol/L] (fill out 999 if it was measured in mg/dL)		<1000
AST [U/L]		<1000
AST ULN [U/L]		<1000
ALT [U/L]		<1000

- 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.



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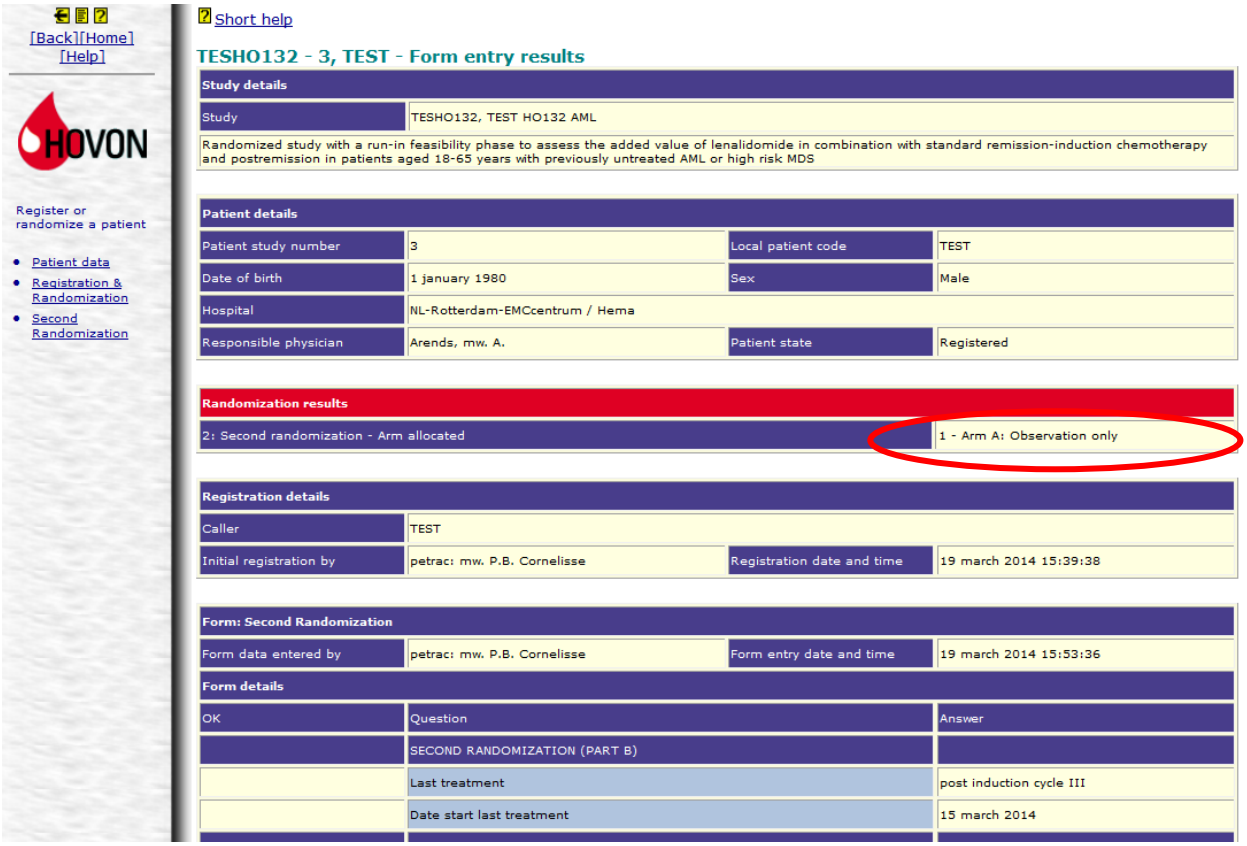
Register or randomize a patient

- Patient data
- Registration & Randomization
- Second Randomization

SECOND RANDOMIZATION (PART B)		
Last treatment	3 - post induction cycle III	
Date start last treatment	15-3-2014	<=##now##
ELIGIBILITY (SEE PROTOCOL SECTION 8)		
Patient in CR(i)	1 - CR	
ANC [10^9/L]	10	<100
Platelets [10^9/L]	100	<1000
Serum creatinine clearance [ml/min]	10	Serum creatinine clearance must be >= 30 ml/min
Total bilirubine [mg/dL] (fill out 9.9 if it was measured in µmol/L)	1	<10
Total bilirubine [µmol/L] (fill out 999 if it was measured in mg/dL)	999	<1000

- 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

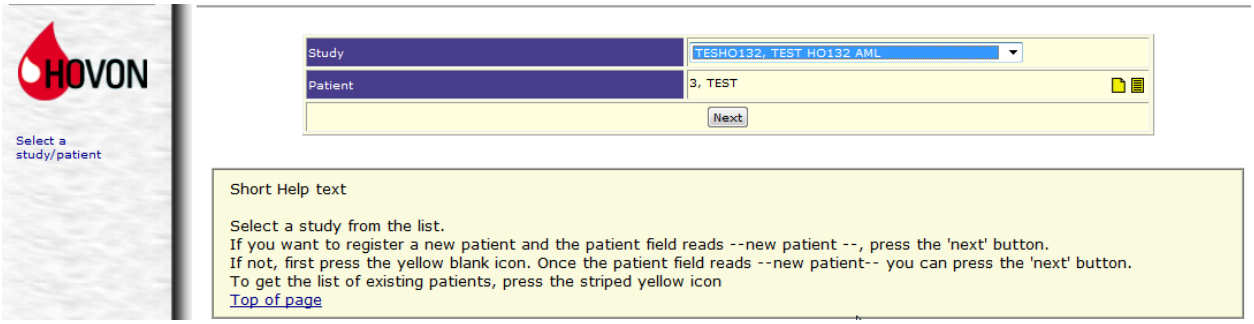
given. After registration TOP will return a screen reporting all answers given and randomization result if applicable. You can print a report by clicking the [Print] button at the bottom of this screen.



- Registration/randomization is finished and you can now safely log out 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.



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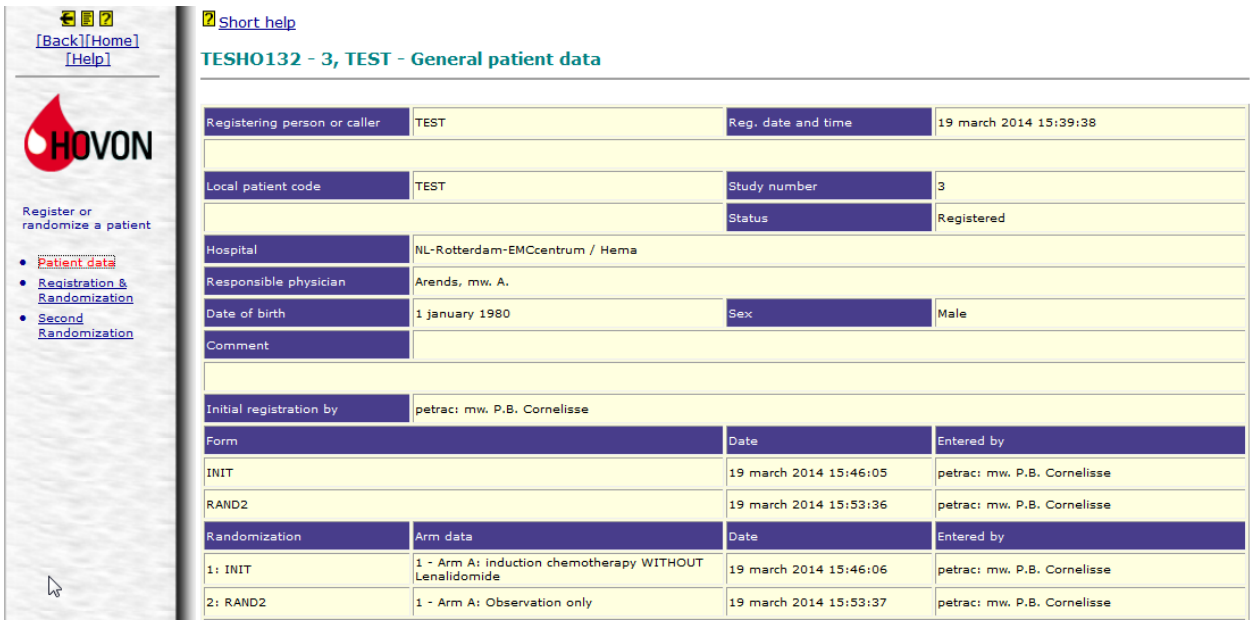
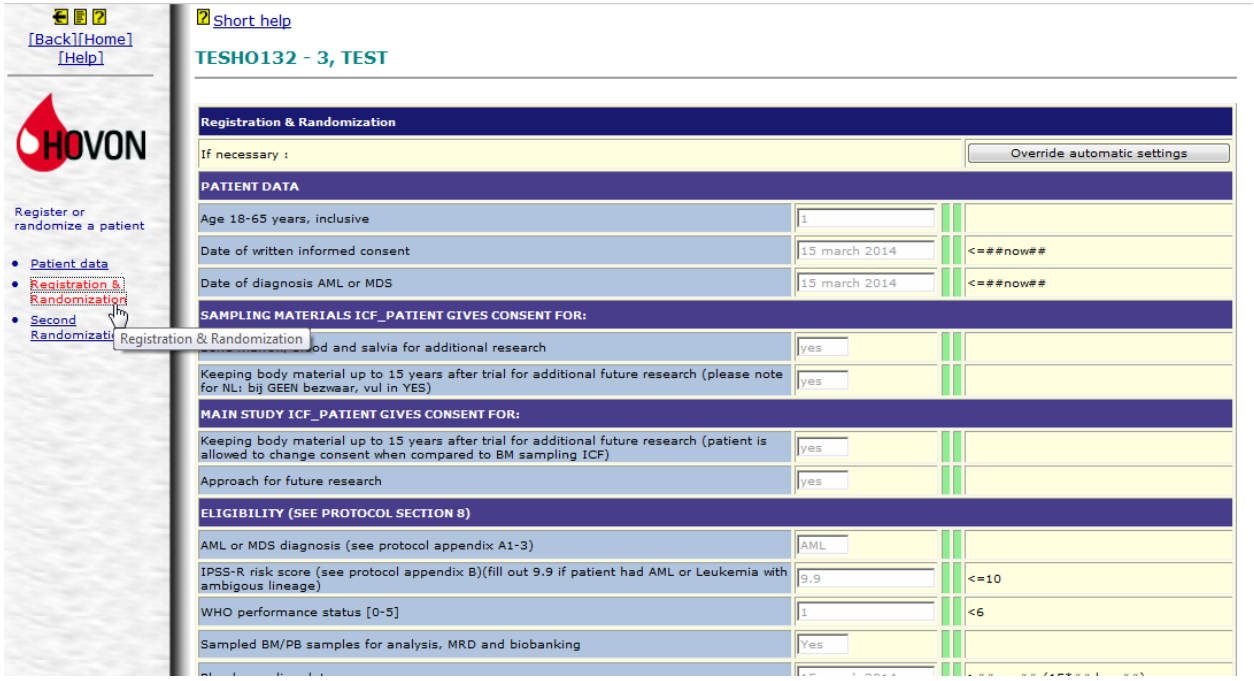


- To review the answers given in a specific form click the relevant form on the left side of your screen.



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 login off.
- If you have trouble entering TOP check the following:
  - Ensure that the URL you typed is https://www.hdc.hovon.nl/top.
- 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…] and try accessing TOP again.
- If you have any questions or problems while using TOP you can contact the HOVON Data Center (tel.: +31 (0)10 704 1560; fax: +31 (0)10 704 1028). In case of technical difficulties, please first check whether or not it is a local problem with your pc or network.