

# 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.....	6
6.	Reviewing existing patients .....	8
7.	Troubleshooting .....	9

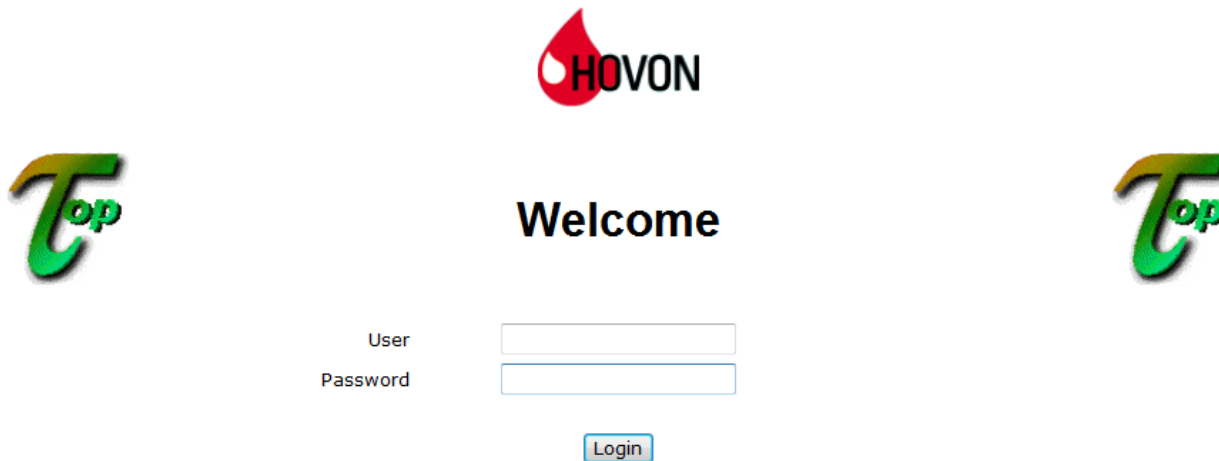
## 2. Prerequisites

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](http://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> .



User

Password

Login

TOP can be used in the following browsers: Internet Explorer, Firefox, Chrome, Opera, Safari.

[Password forgotten?](#)

[Version: 3.2.65]  
[Session: 181481759]

- 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).



Welcome, to the Trial Online Process  
24 hour Registration and Randomization of patients



[Short help](#)

Select an option from the list below

- Patients**
- [Patient registration/randomization](#)
- Reports**
- [Overview reports](#)
- Maintenance**
- [Change Password](#)
- [Logout](#)

Short Help text

Select an option from the menu by clicking once on it. The actual options you see and the hospitals you will be able to get data from or register patients in depend on your user rights. After clicking a menu option, you will get a menu on the left and a page on the right with variable content. Sometimes, you will need to fill out a Web form. To validate there will be a button at the bottom. Only this will send the data to the server.

To get back to this menu, click the 'main menu' option which will be present at all times in the upper left corner. To navigate, either follow instructions, select another menu option or try the 'back' button. The internet is still a somewhat unpredictable medium. Usually, try not to press a button or option twice if nothing seems to happen. You can often verify that something is happening by either looking at the status bar, or by moving the cursor over it. If the program is busy, usually the cursor will change to an hourglass

[Top of page](#)

>>loginlevel W:3 R:3<<

#### 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.

[Short help](#)

[\[Back\]\[Home\]](#)  
[\[Help\]](#)

**HOVON**

Select a study/patient

### Select a Study and a patient

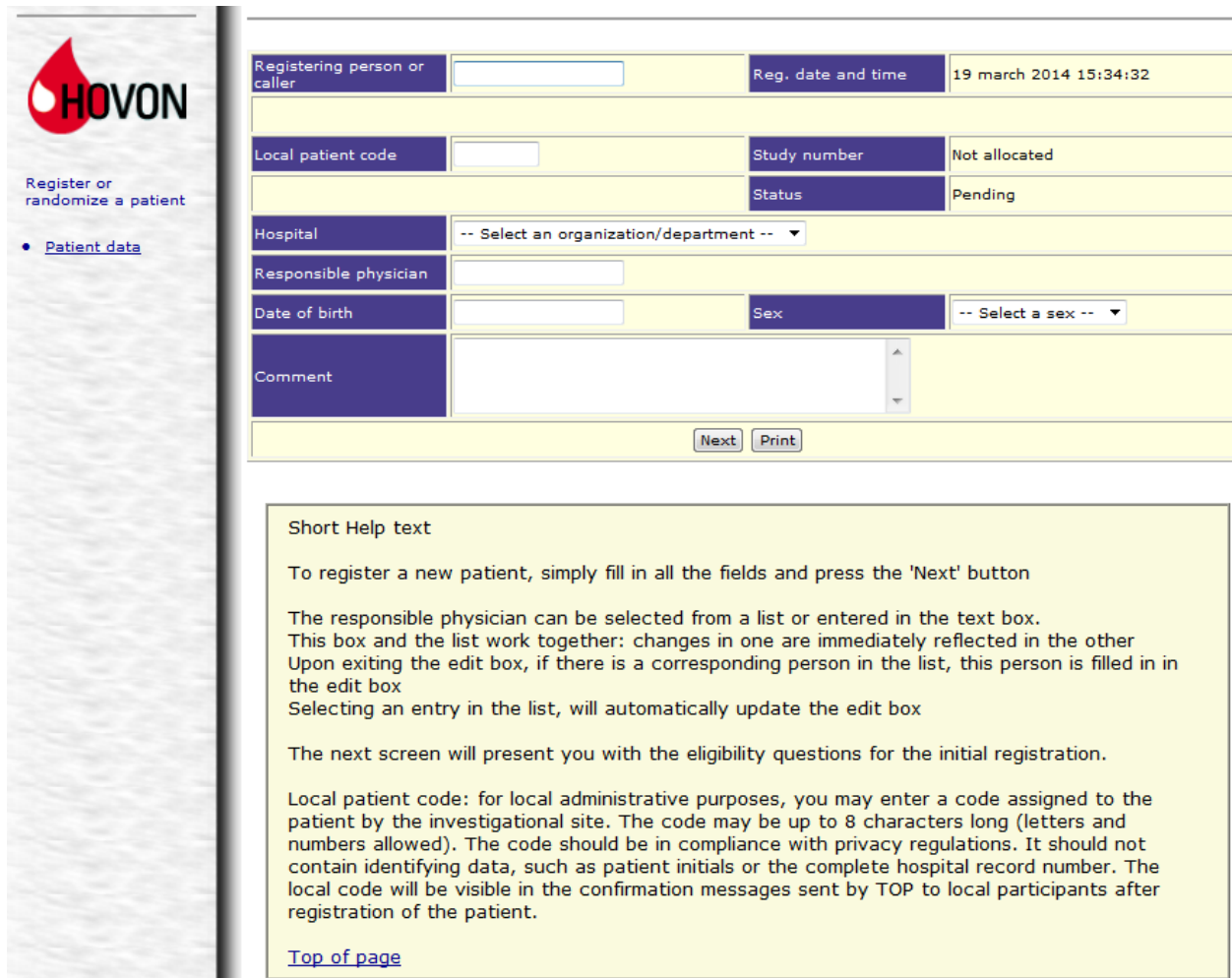
Study	-- Select a study --
Patient	-- select a patient --
<input type="button" value="Next"/>	

Short Help text

Select a study from the list. If you want to register a new patient and the patient field reads --new patient--, press the 'next' button. If not, first press the yellow blank icon. Once the patient field reads --new patient-- you can press the 'next' button. To get the list of existing patients, press the striped yellow icon

[Top of page](#)

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



Registering person or caller  Reg. date and time 19 march 2014 15:34:32

Local patient code  Study number Not allocated

Status Pending

Hospital -- Select an organization/department --

Responsible physician

Date of birth  Sex -- Select a sex --

Comment

**Short Help text**

To register a new patient, simply fill in all the fields and press the 'Next' button

The responsible physician can be selected from a list or entered in the text box. This box and the list work together: changes in one are immediately reflected in the other. Upon exiting the edit box, if there is a corresponding person in the list, this person is filled in in the edit box. Selecting an entry in the list, will automatically update the edit box.

The next screen will present you with the eligibility questions for the initial registration.

Local patient code: for local administrative purposes, you may enter a code assigned to the patient by the investigational site. 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 sent by TOP to local participants after registration of the patient.

[Top of page](#)

- 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 sent 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 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.

Short help

TESHO132 3, TEST - Form entry results

Study details

Study	TESHO132, TEST HO132 AML		
Randomized study with a run-in feasibility phase to assess the added value of lenalidomide in combination with standard remission-induction chemotherapy and postremission in patients aged 18-65 years with previously untreated AML or high risk MDS			

Patient details

Patient study number	3	Local patient code	TEST
Date of birth	1 january 1980	Sex	Male
Hospital	NL-Rotterdam-EMCCentrum / Hema		
Responsible physician	Arends, mw. A.	Patient state	Registered

Randomization results

1: Registration & randomization - Arm allocated	1 - Arm A: induction chemotherapy WITHOUT Lenalidomide
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Registration details

Caller	TEST		
Initial registration by	petrac: mw. P.B. Cornelisse	Registration date and time	19 march 2014 15:39:38

Form: Registration & Randomization

Form data entered by	petrac: mw. P.B. Cornelisse	Form entry date and time	19 march 2014 15:46:05
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Form details

OK	Question	Answer
	PATIENT DATA	
Yes	Age 18-65 years, inclusive	1
	Date of written informed consent	15 march 2014

- 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.

Select a study/patient

Study	TESHO132, TEST HO132 AML
Patient	3, TEST

Next

Short Help text

Select a study from the list.  
 If you want to register a new patient and the patient field reads --new patient --, press the 'next' button.  
 If not, first press the yellow blank icon. Once the patient field reads --new patient-- you can press the 'next' button.  
 To get the list of existing patients, press the striped yellow icon  
[Top of page](#)

- TOP will display the general patient data and a summary of the forms already filled out in TOP.

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 <sup>9</sup> /L]		<100
Platelets [10 <sup>9</sup> /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.

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 <sup>9</sup> /L]	10	<100
Platelets [10 <sup>9</sup> /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.

**TESHO132 - 3, TEST - Form entry results**

**Study details**

Study	TESHO132, TEST HO132 AML		
Randomized study with a run-in feasibility phase to assess the added value of lenalidomide in combination with standard remission-induction chemotherapy and postremission in patients aged 18-65 years with previously untreated AML or high risk MDS			

**Patient details**

Patient study number	3	Local patient code	TEST
Date of birth	1 january 1980	Sex	Male
Hospital	NL-Rotterdam-EMCCentrum / Hema		
Responsible physician	Arends, mw. A.	Patient state	Registered

**Randomization results**

2: Second randomization - Arm allocated	1 - Arm A: Observation only
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**Registration details**

Caller	TEST		
Initial registration by	petrac: mw. P.B. Cornelisse	Registration date and time	19 march 2014 15:39:38

**Form: Second Randomization**

Form data entered by	petrac: mw. P.B. Cornelisse	Form entry date and time	19 march 2014 15:53:36
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**Form details**

OK	Question	Answer
	SECOND RANDOMIZATION (PART B)	
	Last treatment	post induction cycle III
	Date start last treatment	15 march 2014

- 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.

**Select a study/patient**

Study	TESHO132, TEST HO132 AML
Patient	3, TEST
Next	

Short Help text

Select a study from the list.  
 If you want to register a new patient and the patient field reads --new patient--, press the 'next' button.  
 If not, first press the yellow blank icon. Once the patient field reads --new patient-- you can press the 'next' button.  
 To get the list of existing patients, press the striped yellow icon  
[Top of page](#)

- TOP will display the general patient data and a summary of the forms already filled out in TOP.



Short help

TESHO132 - 3, TEST - General patient data

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-EMCentrum / 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	
RAND2	19 march 2014 15:53:36	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
2: RAND2	1 - Arm A: Observation only	19 march 2014 15:53:37	petrac: mw. P.B. Cornelisse

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

Short help

TESHO132 - 3, TEST

Registration & Randomization

If necessary :

PATIENT DATA

Age 18-65 years, inclusive: 1

Date of written informed consent: 15 march 2014 <==#now##

Date of diagnosis AML or MDS: 15 march 2014 <==#now##

SAMPLING MATERIALS ICF\_PATIENT GIVES CONSENT FOR:

Food and saliva for additional research:

Keeping body material up to 15 years after trial for additional future research (please note for NL: bij GEEN bezwaar, vul in YES):

MAIN STUDY ICF\_PATIENT GIVES CONSENT FOR:

Keeping body material up to 15 years after trial for additional future research (patient is allowed to change consent when compared to BM sampling ICF):

Approach for future research:

ELIGIBILITY (SEE PROTOCOL SECTION 8)

AML or MDS diagnosis (see protocol appendix A1-3): AML

IPSS-R risk score (see protocol appendix B)(fill out 9.9 if patient had AML or Leukemia with ambiguous lineage): 9.9 <=10

WHO performance status [0-5]: 1 <6

Sampled BM/PB samples for analysis, MRD and biobanking:

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.