



TENALEA IVRS Randomisation – Randomizing patients by phone

What is TENALEA IVRS Randomisation?

Whereas the web has become very common for randomisation of patients in clinical trials, a certain category of clinical trials still uses standard telephone for patient randomisation. The TENALEA IVRS Randomisation is an Interactive Voice Response System which can be used to support patient registration and randomisation in healthcare research using a standard telephone with a touchpad.

What can a user do with TENALEA IVRS Randomisation?

The TENALEA Interactive Voice Response system (TENALEA IVRS) is designed to enable clinicians and their staff to employ a touch-tone telephone to register and randomise patients in clinical trials.

Using TENALEA IVRS, users can:

- Randomize new patients
- Enter follow up forms for existing patients
- Confirm medication shipments in double blind studies

Access numbers

TENALEA IVRS can be reached by phoning the following numbers

NETHERLANDS: 0031206173947

Using the IVR system

TENALEA IVRS will prompt the user for input. Users will be asked to either:

- Select options from a menu. The system enumerates a list of options along with the number of the key to press on phone to select the option.
- Enter numerical data. The user enters a sequence of digits. In some cases, the user needs to enter data with a decimal point. The user should use the star key (*).

After the user has entered the appropriate values using the keys of his phone, he should wait, and the system will automatically navigate to the next dialog.

Navigating through the application

Here the different dialogs that the user interacts with will be presented. Figure 1 shows the structure of TENALEA IVRS.

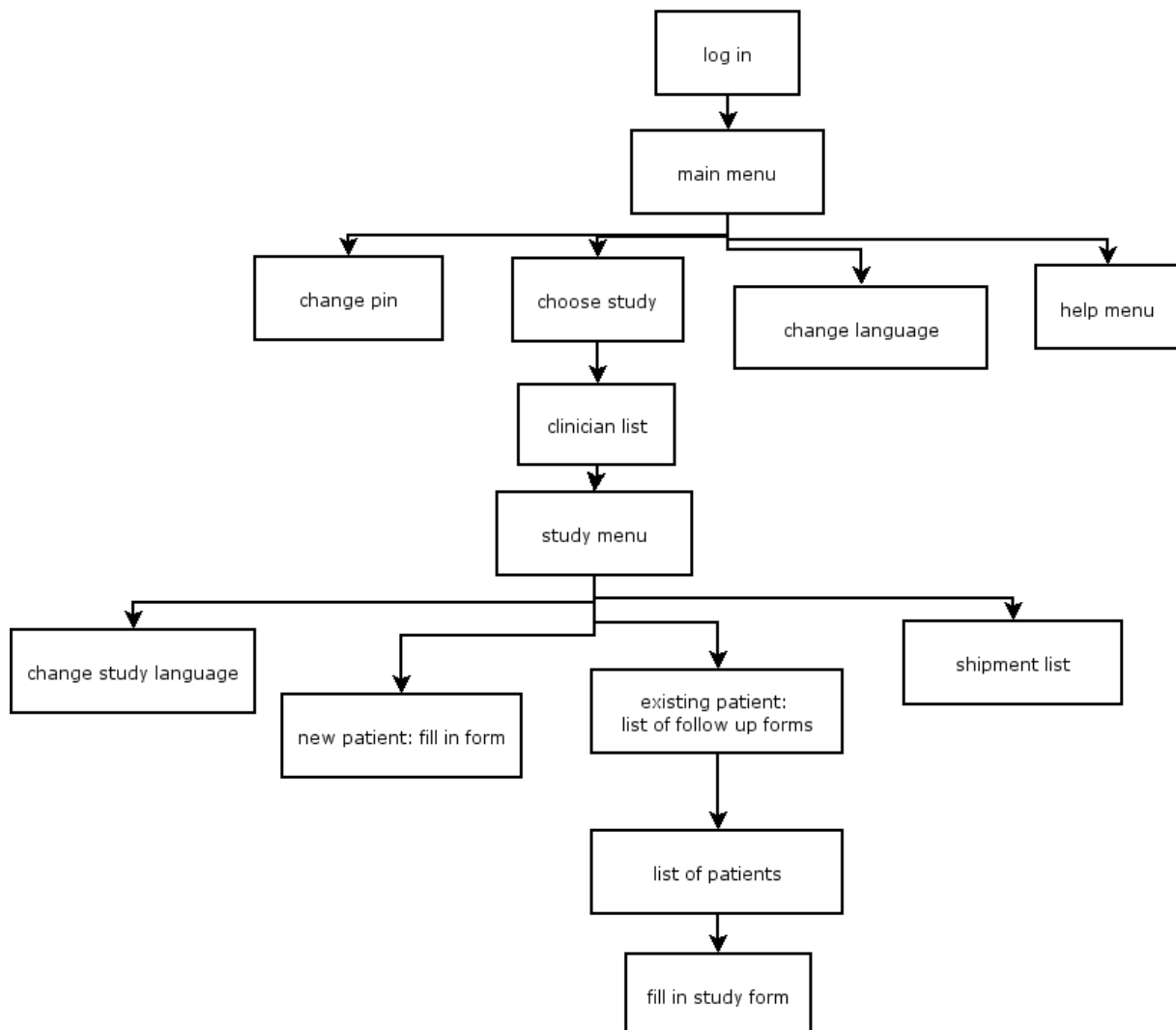


Figure 1: flow chart of dialogs in TENALEA IVRS

1.1 Logging in

The first thing a user has to do is choose the language he wishes to interact with TENALEA IVRS

<system> Press 1 for English, press 2 for French, press 3 for Italian
<user> 1



Then the user credentials have to be entered. TENALEA IVRS users have to be issued with an 8 digit account number and a 4 digit pin number to access the system.

*<system> Please enter your account number
<user> (type the 8 digits here)
<system> Please enter your pin number
<user> (type the 4 digits here)*

If the user enters incorrect credentials, he will be prompted for them again. After logging on, the main menu will be presented (Section 1.2).

1.2 Main menu

This lists the main options available in TENALEA IVRS.

<system> Press 1 for randomization, press 2 for pin number modification, press 3 for language modification, press 4 for help

The user should press 1 to fill in patients forms (section 1.3), 2 to change his pin (Section 1.11) number, 3 to change the language of interaction (Section 1.12), 4 to go to the help menu.

1.3 Choosing a study

The first step to entering data is choosing which study the data relates to.

*<system> Please enter the study code
<user> (Enter the study identification number)*

The user needs to know the identification code of the study he wishes to enter data for. If the number is incorrect, the user will be prompted for it again.

If there are less than 10 studies for which the user can enter data, the system will enumerate the studies, and the user doesn't need to know to code mentioned above.

<system> Press 1 for First Study, press 2 for Second Study.



<user> (Press the number corresponding to the study)

Afterwards the user will be asked for the clinician he wishes to randomize on behalf of (section 1.4).

1.4 Choosing a clinician

All patient data must be entered on behalf of a clinician. It could very well be that the user and the clinician are the same person. In any case the user must select the clinician.

<system> Please enter the clinician code

<user> (Enter the clinician identification number)

The user needs to know the identification code of the clinician. If the number is incorrect, the user will be prompted for it again.

If there are less than 10 clinicians for whom the user may enter data, the system will enumerate clinicians.

<system> Press 1 for Dr. Smith, Press 2 for Dr. Janssens, ...

<user> (Press the number corresponding to the clinician)

When the clinician has been chosen, the user will be presented with the main study menu (section 1.5)

1.5 Study menu

The main study menu presents the possible actions to perform on a study

<system> For a new patient, press 1. For an existing patient press 2. To confirm shipments, press 3.

<user> (Press the number corresponding to the required action)

Selecting a new patient will bring the user to the initial randomization form (Section 1.6), selecting an existing patient will allow the user to select a follow-up form (Section 1.7) and then a patient (Section



1.8). In double blind studies, the system will ask if the user wants to confirm any open shipments; the user will then be told a list of open shipments (Section 1.10).

Studies are defined in several languages, and it may be the case that the user's specified language is not available for the study. If this is so, TENALEA IVRS will prompt the user to select a language which is appropriate for the study at this point. When the user returns to the main menu, the language of dialog will be restored to the user's original choice.

<system> The study is not available in English. Please select a language: press 1 for Dutch, press 2 for Italian.

<user> 1

<system> Voor een nieuwe patient, druk 1.

1.6 Initial randomization form

When entering a patient into an ALEA study, an initial allocation form needs to be filled in. The structure of this form is similar to a follow-up form, so the reader is referred to the follow-up form section (Section 1.9) for instructions on an initial form.

1.7 Form list

For existing patients, a form has to be selected

<system> For pathology form, press 1. For radiology form, press 2.

If there are more than 10 options, TENALEA IVRS won't enumerate the forms, and the user will need to know the form identification code.

<system> Please enter the form code

<user>(Enter the form ID code)

After a form has been selected, a patients needs to be chosen. (Section 1.8)

1.8 Patient selection

The user has to select a patient to fill in a form for



<system> Please enter the patient code

<user> (Enter the patient ID code)

Once the patient has been selected then the form is ready to be filled (Section 1.9)

1.9 Follow-up form

In ALEA, study administrators define forms which contain questions. TENALEA IVRS presents these questions in succession. There are several types of questions (shown here with an example):

Natural number:

<system> please enter the patient height

<user> 180

The user should enter the succession of digits and pause when he is done.

Numerical:

<system> Please enter the blood cholesterol level. Use the star key as a decimal

*<user> 2*60*

The user should enter the succession of digits using the star key (*) of the phone to signal a decimal point and then pause.

Categorical:

<system> Please enter the VP Scan result. For Low press 1, for Intermediate press 2, for High press 3.

<user> 2

The user should select the appropriate option from the list and pause.

Logical:



<system>Has the patient filled in the informed consent form? Press 1 for yes, press 2 for no
 <user> 1

The user should press 1 for an affirmative answer or 2 for a negative answer and then pause.

Date:

<system> Please enter the date of birth. Enter the year first, then the month followed by the day.
 <user> 19790131

The user should enter a succession of digits. The first 4 digits are the year, the following 2 digits are the month, and the last 2 are the day. There is no punctuation between the fields. The user should then pause.

Text:

This is the most difficult data type to enter via the phone. TENALEA IVRS users are advised to read the next section carefully.

TENALEA IVRS assumes that users have in front of them a standard ITU E 1.161 keypad:

1	2 ABC	3 DEF
4 GHI	5 JKL	6 MNO
7 PQRS	8 TUV	9 WXYZ
	0	

Under each of the number keys, there are letters. Because there are 26 letters, and only 10 numbers keys, two keys have to be pressed to enter one letter. For instance, the letter "A" is entered by typing the digits "21" in succession on the keypad. If digits have to be entered, the user has to type in the required digit followed by "0". For instance for the digits "34", the user should type "3040". A space character is designated by "11".

Below is a table of characters and their corresponding number sequences:



Required Character	Numbers to press on keypad
A	21
B	22
C	23
D	31
E	32
F	33
G	41
H	41
I	43
J	51
K	52
L	53
M	61
N	62
O	63
P	64
Q	71
R	72
S	73
T	81
U	82
V	83
W	91
X	92
Y	93
Z	94
1	10
2	20
3	30
4	40
5	50
6	60
7	70
8	80
9	90
0	00
SPACE	11

An Example:

When the user has finished entered the succession of digits, he should just wait.



An example:

```
<system> Please enter the patient's name
<user> 226322117461438142
<system> You entered Bob Smith. Is this correct? Press 1 for yes, press 2 for no.
<user> 1
<system> Please enter the patient code?
<user> 2110
<system> A1
```

Ineligibility

Some values make the patient ineligible for the study. The system will warn the user and ask him if he wants to enter a new value:

```
<system> Please enter the patient height
<user> 190
<system> This will make the patient ineligible. Press 1 to cancel the form, press 2 to enter a
new value.
<user> 2
<system> Please enter the patient height
<user> 160
```

Answer confirmation

For some studies, confirmation of answers is required after every question. The answer the user entered will be repeated and has to be confirmed by the user by pressing 1 to continue. If the user wishes to enter a new value instead, he must press 2. Here's an example of a user entering and then correcting a value.

```
<system> Please enter the patient number
<user> 123
<system> You entered 123. Is this correct? Press 1 for yes, press 2 for no
<user> 2 (no)
<system> Please enter the patient number
<user> 124
<system> You entered 124. Is this correct? Press 1 for yes, press 2 for no.
<user> 1
```



Form submission

Once the form is finished, TENALEA IVRS will ask for a confirmation and then submit the form.

If any randomizations are attached to the form, TENALEA IVRS will reveal the outcome of the randomization

<system> The form is finished. Press 1 to submit it, press 2 to cancel

<user> 1

<system> The form has been submitted, the patient number is 123. In the randomization aspirin versus novirax, the patient has been allocated treatment aspirin.

1.10 Confirm shipment

In double blind studies, a list of shipments to confirm will be given by TENALEA IVRS

<system> For shipment 1 sent on September 2, press 1. For shipment 543 sent on January 23, press 2.

<user> 1

<system> shipment confirmed.

1.11 Change pin

This menu allows the user to permanently modify their 4 digit pin number

<system> Please enter your new pin number

<user> 5678

<system> Please enter your number again

<user> 5678

<system> Your pin has been successfully changed.

If the numbers don't match, the user will be prompted again.

1.12 Change language

This menu allows the user to change the language of interaction with TENALEA IVRS

<system> Please select a language. Press 1 for Dutch, press 2 for French.



<user> I

<system> *The language has been successfully changed.*

<system> *Welkom bij TenAlea.*

More information

For further information, please contact the TENALEA Information Desk at +31-20-512.2671 or email info@tenalea.net