

## On-line tutorial - EpiNet-First trials

Patients are registered in the standard way, using the "Add Patient"  icon from the ribbon at the top of the page.

This will bring up the Demographics form.

If you wish to enter a patient into the '**First AED registry**', you can do so from this page. Note that if you choose this registry, ***the patient will not be eligible for any of the EpiNet-First randomised controlled trials.***

## Entry into one of the EpiNet First trials

Eligible patients will be randomised on-line immediately, once it is confirmed that the patient is eligible, and that the patient (or an appropriate care-giver or parent) has signed a consent form.

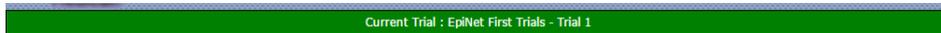
Trials are open, and the investigator will be immediately informed of the drug to which the patient has been assigned.

The particular trial into which a patient is entered will be determined by the patient's seizure type, and the suitability of Sodium Valproate.

Patient information and consent forms can be printed from the 'Resources' tab, which can be accessed by choosing the "Trials" tab on the ribbon at the top of the record. (These forms can also be accessed via the Public Website ([www.epinet.co.nz](http://www.epinet.co.nz))).



Once a patient has been entered into a trial, the ribbon on the patient's record will change to show a green bar at the top. The patient's status in the trial will be shown at the top of the summary page.

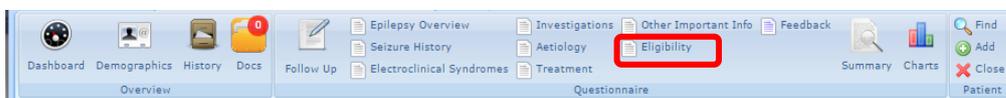


## Eligibility for trials:

All the questions that determine whether a patient is eligible for a trial are contained on the Overview form and the Seizure-Types form. The eligibility can therefore be checked after these two forms have been completed. (Eligibility can also be checked after all the forms have been completed.)

Eligibility can be checked either:

- by choosing the 'Eligibility' icon from the ribbon, or



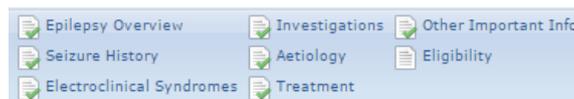
- by returning to the summary page and clicking on the "Check eligibility for EpiNet-First trials" link.



Although it is possible to enter and randomise a patient before all the forms are completed, it is still essential to complete all the forms so that the record can be marked 'Up to date.' Important information for the trials is contained in some of these other forms.

A 'Snapshot' of the record is taken immediately after a patient is randomised, (before the treatment record has actually been completed.) The snapshot records the information in the record at that particular time.

A second snapshot is taken once the entire record is marked 'Up to date.' For this to happen, each of the forms needs to be submitted and marked as 'Up to date' - indicated by a green tick.



These snapshots are available for review from the 'Docs' icon on the ribbon.



## Overview Form

To be eligible for a trial, the following are required:

- The Level of confidence that the patient has had one or more epileptic seizures must be Probable or higher
- The Current epilepsy status must be 'Second seizure' or 'Epilepsy with more than 2 seizures'.
- The question: "Are the patients seizures due to a known progressive neurological disease?" cannot be answered 'Yes'
- The patient cannot have either Acute symptomatic seizures or Psychogenic Non-epileptic seizures
- The question: "Has the patient ever been treated with an antiepileptic drug for epilepsy for more than one week?" must be answered 'No'
- The question: " Have the seizures been provoked by alcohol or recreational drugs?" cannot be answered 'Yes'

## Epilepsy Seizure History Form [Epilepsy Seizure History](#)

If a patient has more than one seizure type, all the seizures should be recorded. Please fill in a new form for each seizure type.

Seizures are now grouped together into broad categories.

For the purposes of the **EpiNet-First** trials, we want patients who clearly have **focal** (or partial) seizures to be entered into the trial for people with focal seizures.

We **ONLY** want patients who have **genetically determined generalised seizures** to be enrolled into the trials for patients with generalised seizures. For the purposes of these studies, we want investigators to use the following criteria for diagnosing generalised seizures:

No clinical features to suggest focal seizures, *and either*

- Generalised spike and wave on EEG, *or*
- Myoclonic seizures, *or*
- Generalised tonic clonic seizures alone with onset below age 30, provided that all seizures have NOT occurred from sleep

***If these criteria are not met***, then patients should be entered into one of the trials for patients with seizures of uncertain nature. In particular if you do not know whether there could have been a focal onset to someone's seizure, you should choose the seizure type: "Epileptic seizure, uncertain if generalised or focal"

(There is also an option under the Generalised seizures heading: "Generalised- uncertain if generalised from the outset or of focal origin." If this seizure type is chosen, the patient will be entered into one of the trials for seizures of unknown nature (uncertain if generalised or focal.))

On the seizure history form, it is possible to record dates of each seizure; this may be impractical if a patient is having frequent seizures, but we would like dates recorded as precisely as possible if a patient has experienced infrequent seizures.

If exact dates are entered, they will be tallied and displayed automatically in the seizure diary.

## Treatment form [Epilepsy Treatment](#)

The record will default to show the drug to which the patient was randomised. It is possible to change this, but if you do not prescribe the assigned drug, the trial will be undermined, and you will be asked for an explanation. (The patient should not be entered into a trial unless both the doctor and the patient are prepared to take any of the possible AEDs for the particular trial.)

Please record as accurately as possible what you intend the patient to do; it is possible to record how a drug is being titrated (either upwards or downwards.)

You will be asked to confirm at a later date that the patient did actually follow the proposed course of treatment. (If a drug is being titrated, it is not possible to confirm the dose until after the target date has arrived.)

If something other than what was planned actually happened, then do not confirm the inaccurate data; instead, choose the 'Change' option and record what did actually happen.

Side effects can also be recorded on this form. (Note that we are recording serious adverse events as a secondary endpoint of the trials, but we are not recording side effects as a formal endpoint.)

## Serious Adverse Events Form Epilepsy Serious Adverse Events

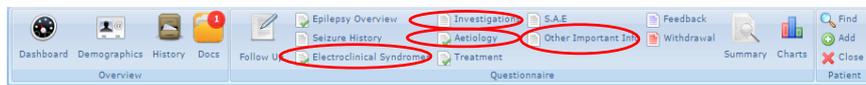


This is a new form, which has not been available in the standard EpiNet database.

The definition of a serious adverse event (SAE) can be found in the protocol and on the form itself.

Whenever an SAE is recorded, an e-mail is automatically forwarded to the EpiNet administrator.

## Please Complete Other forms



It is important that the "Electroclinical syndromes' form", "Investigations' form", "Aetiology form", and "Other Important Medical Information form" are also completed when a patient is entered into a trial. The information on these forms is not required for the patients to be randomised, but the information will be required when analysing the results. Completion of all these forms should be straightforward. The approach to the forms is exactly the same as in the standard EpiNet database.

When all these forms have been completed, the record will be marked as 'Up-to-date.'

## Follow Up

Each patient needs to have the record updated at pre-determined intervals (3 months, 6 months, 12 months, 18 months and 2 years). Records can also be updated at other times. Snap shots are taken at the pre-determined intervals, but not outside of these time periods.

It is most efficient if you complete the follow up using the follow-up pop-up from the ribbon at the top of the patient's record.

Depending on the answers you give to the questions on the pop-up, you will be taken to the appropriate forms to update them. If you wish, you can simply choose a particular form to update that form outside of the predetermined follow-up windows.

## Trials Tab



If you choose the 'Trials' tab from the ribbon at the top of the record, you can bring up summaries of the **EpiNet-First** trials.

The Resources tab will enable you to print any of the patient documents for the trials.

Clicking on any of the Trial icons will show all of the patients in your cohort in that particular trial.

The Trials report gives an overview of each investigator's patients in the trials. (This report shows the results for each investigator, as opposed to the entire cohort.)

The 'Eligibility check's tab  will check to see which patients an investigator has entered into the database who might *potentially* be suitable for any of the **EpiNet-First** trials