



## Recruitment at 30 April 2007

Total number of  
patients recruited per  
country

UK	308
Singapore	140
Poland	78
China	68
Canada	22
Philippines	16
New Zealand	11
Australia	8
Hong Kong	4
Belgium	0
Sri Lanka	0
Malaysia	0

**Total number of  
patients recruited  
to date on 30  
April 2007**

**655**

ENOS

## The Newsletter for the Efficacy in Nitric Oxide Stroke Trial

Web: [www.enos.ac.uk](http://www.enos.ac.uk) Email: [enos@nottingham.ac.uk](mailto:enos@nottingham.ac.uk)

## European Stroke Conference 2007

We look forward to meeting colleagues at the ESC in Glasgow from 29 May – 1 June. We are hosting an Investigator Launch Meeting on Tuesday 29 May in the Crowne Plaza Hotel from 12 noon, with buffet lunch and presentations throughout the afternoon. We will be hosting a stand, number 143, in the Exhibition Hall and look forward to seeing colleagues there too.

## UK Investigator Meeting

We are hosting a UK Investigator Meeting at the University of Nottingham, Jubilee Campus on 11/12 September 2007. Please make a note in your diaries and confirm attendance to [Yvonne.Smallwood@nottingham.ac.uk](mailto:Yvonne.Smallwood@nottingham.ac.uk). Agenda to follow.

## Congratulations to...

- Torbay Hospital, Torquay, UK for randomising their first ENOS patient.
- Stepping Hill, Stockport; Bishop Auckland, UK; Singapore General Hospital and Dunedin, NZ for randomising 5 patients since 1 November 2006 and achieving their £100 bonus.
- Wenzhou, China for recruiting 18 patients in February 2007, the highest for one centre in one month and a continued sustained high level of recruitment.
- Stepping Hill, Stockport for recruiting the 600<sup>th</sup> ENOS patient.

## Tip of the month

We now have an ENOS "demo" site, which can be found at: <http://www.nottingham.ac.uk/stroke-medicine/enos/enostrialdb/demo/>  
There is a demo country, centre and investigator. To log in use the investigator id "demoinv1" with password "nottingham" and pin "8888".

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## Stroke Research Network Launch Meetings

We have been touring the UK to visit all the Stroke Research Network Launches and have enjoyed meeting many existing and new colleagues. See photo below at West Midlands Stroke Research Network Launch at the University of Keele, Staffs on 30 March 2007.

Left to Right:  
Dr Gillian Sare, ENOS Trial Medic  
Dr Christine Roffe, Clinical Lead, W. Mids. Local Research Network  
Dr Kathryn Wilde, Network Manager, W. Mids. Local Research Network



## SUSARs

For those of you unfamiliar with the term SUSAR, it is a term introduced by the EU Clinical Trials Directive as a way of collecting data on adverse reactions in clinical trials. A **SUSAR** is a Suspected Unexpected Serious Adverse Reaction to a drug. The ENOS database now includes this term on the SAE form.

It is worth emphasising that a SUSAR is a **serious drug reaction** (therefore not just an SAE) that has to be **unexpected**, i.e. not a recognised reaction to the drug or consequence of the medical condition it is used to treat. If an investigator declares a SUSAR we have a legal obligation to report the event to the MHRA, UK Regulatory Agency, within 24 hours.

GTN is a very long established medication and a SUSAR in the context of the ENOS trial is very unlikely. We have prepared Standard Operating Procedures to guide you as to when a reaction may be a SUSAR and crucially, when it is not.

**If in doubt, please contact us rather than declare a SUSAR incorrectly.** Please also contact us if you have further questions on this issue.

### \*\*\*\*\*Recently Updated Forms\*\*\*\*\*

- \* File note form v1.0
- \* Contents for Investigator and Patient Site Files v1.1
- \* ENOS Protocol Summary v1.5
- \* SOPs: Randomizing if the web site is down; Trial Management Committee; How to write an SOP for ENOS, SUSARs v1.3
- \* Reminder: We are on v2.8 of all Patient/Relative Information Sheet and Consent/Assent forms.

All forms can be downloaded from the web site: [www.enos.ac.uk](http://www.enos.ac.uk)

**ENOS now has 41 centres in 12 countries.  
More centres are welcome.**