



# PD MED Newsletter



September 2007

**PD MED** is a large, simple, 'real life' trial that aims to determine more reliably which class of drug provides the most effective control, with the fewest side-effects, for both early and later Parkinson's Disease.

## PD MED recruitment has been extended

We are pleased to inform you that recruitment into the **PD MED** trial will now continue until December 2008. Recruitment had been due to close in December 2007 but there was a strong consensus at the Trial Steering Committee meeting in May that recruitment should be extended for an additional year. The rationale for continuing randomising beyond the previously scheduled closure date of December 2007 is that:

- ◆ **PD MED** still needs more patients: there are 1079 in the early PD comparison (target 1000-1500) and 331 in the later disease comparison (target 500-750)
- ◆ The DeNDRON Local Research Networks are only now becoming fully functional and the recent surge in recruitment suggests that the numbers randomised will be substantially increased by extending recruitment
- ◆ The number of people in the early randomisation whose PD has progressed such that they become eligible and are randomised in the later disease comparison is increasing steadily and thus extending recruitment would be particularly useful to meet the later disease target recruitment

The decision to keep recruitment open until December 2008 was also strongly supported by **PD MED** Collaborators at the May meeting. It was considered that, until **PD MED** results become available, there will remain uncertainty about the relative benefits of the different classes of drug for Parkinson's disease and hence that randomisation into **PD MED** remains a better option than a haphazard choice between drugs outside of the trial. The decision to extend recruitment is also supported by the Data Monitoring and Ethics Committee and by the NHS Health Technology Assessment Board who fund **PD MED**.

## Recruitment Prizes..!

We are approaching the randomisation of our 1,500<sup>th</sup> patient and to commemorate this milestone we are offering prizes of chocolate & champagne for the centre who enter the 1,500th patient into the trial.

We will also be offering a prize for the centre with the most improved recruitment between September - December 2007.

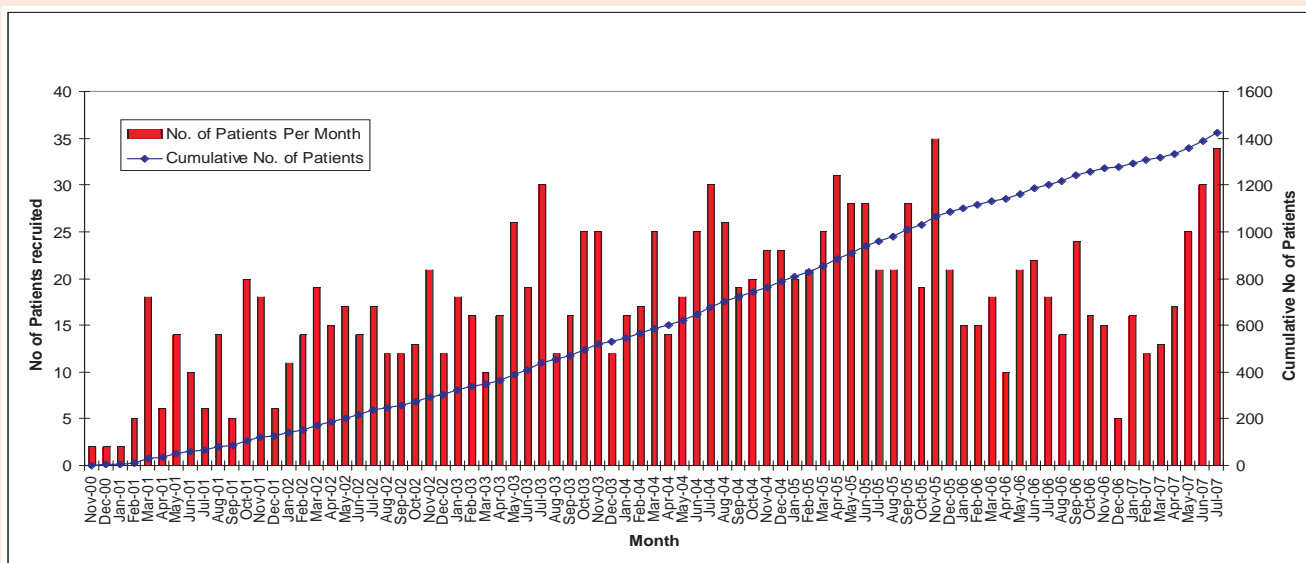
Congratulations to City Hospital, Birmingham for recruiting their 100th Patient.



## Recruitment into the later arm of the **PD MED** study

As time progresses, more patients who were initially randomised into the early part of the trial will become eligible to be re-randomised into the later stage. We will be sending out reminder letters to centres that have patients that are eligible to be re-randomised. We are also going to send out a simple diagram of the process to all centres to help clear up any confusion about when patients are eligible to be re-randomised. If you have any questions about the criteria for entry, or re-randomisation, into the later stage of the **PD MED** trial, please contact us.

## PD MED Recruitment Update



July has been our 2nd best recruiting month ever. There has been a clear improvement in recruitment in the last 3 months including an increase in recruitment to the later stage of the trial. This appears to be a combination of the usual benefit of the Collaborators' meeting and the DeNDRoN support that **PD MED** is receiving. We hope that this benefit will be seen in the rest of the country once the CRN regional centres are up and running.



### PD MED Collaborators' Meeting 2008

**Save this date:** The 2008 Collaborators' meeting will take place on the 8-9th May in Birmingham as usual. This meeting will be held jointly with that for the PD SURG trial which will be presenting the comparison data between immediate DBS surgery and best medical therapy for the first time. PD SURG is the largest randomised, controlled trial to compare DBS surgery with medical therapy to date.

**Reminder:** Please ensure that you keep a copy of all of the consent forms in the investigator's folder. A complete set of copies of consent forms were included when the folders were sent. If you have any consent forms missing from this folder, if you let us know we will be happy to make copies for you. This is the type of information that has been checked when sites have been audited and so it is important that this information is up to date. When the next batch of consent forms is printed we will get a 5th sheet added for this purpose, until then, please make a copy or get us to send a copy to you.

BCTU has moved to Division of Medical Sciences, Robert Aitkin Institute, University of Birmingham, Birmingham. B15 2TT.

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**Thank you again for taking part in the PD MED trial.**

**PD MED** is funded by the NHS through its Health Technology Assessment research programme. It is supported by the Parkinson's Disease Society, the European Parkinson's Disease Association and the Parkinson Disease Specialist Nurse Association.

