



# The MFMU Networker

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## Newest Network Trials Going Nicely

### *STTARS Recruitment Excels*

Recruitment into the STTARS trial, which is investigating whether hydroxyprogesterone caproate prevents preterm birth in multifetal gestations, continues to exceed original goals with about 31 randomized during each of the past three months in the twin stratum and 5 randomized in the triplet stratum. This trial, with a required total sample size of 720 patients has only been recruiting for little over a year. If this rate continues, the trial could complete recruitment within the year, finishing with 600 women with twin gestations and one hundred twenty women with triplet gestations!

The multi-center ancillary study, which is studying the pharmacodynamics and pharmacokinetics of progesterone, has been revised to make the pelvic exam to collect cervical secretions for signs of infection optional for the patient. The blood draw to collect about 30 cc of blood at two visits (between 24 to 28 and again between 32 and 35 weeks of pregnancy) remains the same. The blood draw and pelvic exam are capitated separately.



### *Smooth Start to Omega-3 Trial*

The purpose of this new trial is to determine whether Omega-3, a polyunsaturated fatty acid nutritional supplement in addition to injections of progesterone decrease the rate of preterm birth in women at risk. Wake Forest was the first Network center to randomize a patient into the Omega-3 trial at the end of January. Since then 17 patients have been randomized and all but one center has been certified. Wake Forest and Wayne State Universities have both randomized four patients. It was estimated, based on the previous progesterone trial, that nineteen patients per month will be randomized. As centers get up to speed, it is expected that this target will be reached.

Thus far, the shipping of patient blood specimens to three separate labs is going well. Centers are reminded to make sure to include enough dry ice in the packaging. The shipping instructions contained in the study's manual of operations are being checked to make sure they comply with the International Air Transport Association guidelines.

## 2004-2005 is Busiest Year for Network

This has probably been the most productive year ever experienced by the Network. Four full scale studies (CAPPS Prediction, STTARS, Progesterone Follow-up, Omega-3) were started during the budget year. In addition to maintaining five ongoing studies (BEAM, BEARS, GDM, FOX, and CAPPS RCT), the Network also implemented two ancillary studies (STTARS-Pharmacodynamics and FOX-

Meconium). In ten months the BCC and investigators worked on 66 separate analyses; 46 of these analyses involved manuscripts whether published, submitted, revised, in the review process or in draft format.

During the year, the BCC and investigators also worked on 23 abstracts (21 presentations, 2 withdrawn/rejected). Up to 11 additional manuscripts will be

generated from the presentations, the majority before the end of the budget year. Thus by the end of March 2005, more than one manuscript per week has been worked on. In addition, there are seven ongoing analyses not currently designated for a particular meeting, which are likely to result in further manuscripts. In comparison with prior years, 2004 was also prolific in terms of full length peer reviewed publications (13); only one previous year has equaled that number.



## NICHD Issues RFA for MFMU Network

On February 4, 2005, the National Institute of Child Health and Human Development (NICHD) released its RFA inviting investigators to participate with the NICHD "under a cooperative agreement in an ongoing multi-center clinical program (the MFMU Network) designed to investigate problems in clinical obstetrics, particularly those related to prevention of low birth weight, prematurity, and medical problems of pregnancy." The NICHD intends to commit approximately \$10.3 million in total costs [Direct plus Facilities and Administrative (F & A) costs] in FY 2006 to fund 13 to 16 new and/or competing continuation grants in response to this RFA.

Letters of intent are due to NICHD by June 22 and the application is due July 22. The peer review will take place in October/November and the Council review date is in January 2006. For further information, please go to the url:

<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-04-023.html>

## CAPPS Update

The purpose of this randomized clinical trial is to evaluate the effects of antioxidant therapy (vitamins C and E) in preventing serious complications associated with pregnancy related hypertension in low risk, nulliparous women.

Recruitment to the CAPPS trial has significantly increased over the past three months and seems to be stabilizing at about 200 patients across the Network per month. With a required sample size of 10,000 for the trial, the Universities of Utah and Alabama lead the way with 448 and 291 patients respectively, out of the Network's currently randomized total of 2495 as of March 3. The increased recruitment may be the result of the centers having more staff available since the FOX trial ceased, the effects of spreading recruitment out to local physician offices, and the "site visit" conference calls held last December with the resulting list of strategies and tips. "Site visit" conference calls will continue to be held with those centers that are not able to maintain their recruitment rates.

The first batch of about 1000 samples of patient blood drawn at randomization, study visits and delivery, in addition to cord blood, is being sent to the lab at the University of Minnesota for quality control testing of vitamins C and E.

Meanwhile, 107 of the 4000 patients needed for the prediction component of the CAPPS trial, which is measuring potential biochemical and biophysical markers for the prediction of preeclampsia, have been enrolled. Centers have been urged to encourage recruitment.

## GDM Update

This randomized trial of patients with a normal fasting glucose level is being conducted to determine whether mild gestational diabetes is a risk factor for adverse perinatal outcome and whether there is utility in identifying and treating patients with mild disease. The study, which has been going for about three years, compares patients who have been randomized to diet therapy with patients who have been randomized to no treatment. While recruitment picked up to about 40 patients per month before the end of last year, it has dropped off to about 30 per month. About 720 patients have been recruited to Groups 1 and 2 out of the 900 required. Centers are urged to increase enrollment (*cont'd next column*)

to Group 3, which is running about 50 patients behind the other groups.

To assuage physicians who have expressed concern about not knowing their patient's OGTT results if they are randomized to the trial, OGTT results for Group 2 patients will be sent to the nurse coordinator in a sealed envelope to hand over to the physician or patient after she delivers. In addition, research nurses have been told that they can contact Group 2 and Group 3 patients multiple times after 36 weeks gestation in order to keep in touch and to encourage patients to notify them when they deliver so their samples can be collected.

## BEAM Training Held at Kennedy Krieger

The annual training and review for the physicians who conduct developmental exams on the infants born in the BEAM trial at 6, 12, and 24 months was held at the Kennedy Krieger Institute in Baltimore on March 21. Eleven examiners from nine centers participated in the one day, hands-on workshop. On a related note, all Bayley examiners certified for the two-year BEAM and BEARS assessments are reminded that a videotaped Bayley exam is due to Terri Leach by May 31.

## Proposed Abstracts Submitted for SMFM

March 31 is the deadline for proposed abstracts for SMFM to be submitted to the respective protocol subcommittees. During the first two weeks of April, the subcommittees will hold conference calls to evaluate, approve/disapprove and prioritize these proposals and to inform the Publications Committee of their decisions. The Publications Committee will prioritize the submissions across all studies at the April Steering Committee meeting.

A total of 39 proposed secondary analyses have been submitted for 8 completed Network studies: Preterm Prediction – 3, Preterm PROM – 2, C-Section – 19, Progesterone – 8, BEARS – 2, FFN – 2, BVfFN Cohort – 1 and Factor V Leiden – 2.

## Monthly Reports Now E-Mailed

Beginning with February 2005 data, the monthly reports including screening, randomization and other patient status numbers and the capitation reports, are now being e-mailed by the BCC to the Network PIs, Nurse Coordinators and NIH. It is expected that this new procedure will expedite the dissemination of information and also result in substantial savings of paper and postage.



## DSMC Reviews Network Trials

The Network's DSMC met February 18, 2005, to review all six of the ongoing Network trials. Dr. Cathy Spong will report their recommendations at the April Steering Committee. The ensuing DSMC report for the IRBs will be sent to the Centers shortly.

## Nurse Coordinators Arrange NICHD Grants Management Seminar

Coordinators Kris Anderson (Utah) and Michelle DiVito (Drexel) have worked with Maggie Young, the Network's Grants Manager at NICHD, to plan a workshop for the grants management personnel from each of the University centers. The event will take place on Wednesday, April 20, from 9-3:30 at NICHD. Various members of the NICHD grants staff will be presenting topics specific to the MFMU Network grant, including an overview of the cooperative

agreement mechanism, the annual progress report, compliance, quarterly financial reports and draw-downs, annual FSRs and carryover requests, and a review of cost principles.

All fourteen of the Network centers, plus the BCC, will have representatives attending the meeting. Attendees have been encouraged to submit their questions in advance by e-mail.

## MFMU Website Modifications

The public access portion of the Network's web site has been changed, and has been submitted to the GWU IRB for approval, to allow recruitment information to be posted for the Network's ongoing studies. Though the Network's studies are listed on the NIH Clinical Trials web site ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)), it is hoped that the additional exposure about the studies, will help recruitment overall. Within the last month, nearly 2000 people logged onto the Visitor's Center.

Members of the Network are also heavy users of the Web site's Business Center. Peg Cotroneo, coordinator at Magee, is the top user with 346 "hits" over the past six months. Next to Peg, Karen Dorman is the coordinator with the second highest use of the web with 174 hits. Dr. Patrick Ramsey at the University of Alabama has used the web site the most of any investigator (147 times) over the past six months, while Dr. Dwight Rouse, also at UAB, is the Principal Investigator to use the web site the most (62 times). There was a total of 7013 usage sessions on the Business Center between September 28 and March 28, 2005.

## People in the News

► **Congratulations to Dr. Cathy Spong**, the Network's NICHD Program Scientist, on the birth of her son, Winston Kiel Gruver, who was born February 20 at 8:16 pm. He weighed 7 lbs 0.7 oz and was 20 inches long. He took his first airplane ride on March 17 to accompany his mother to Las Vegas for a meeting.



► **And the Winner is...Dr. Michael DiPietro**  
Dr. DiPietro was the first of six people to compute the correct answer and respond to the Brain Teaser Contest in the December *Networker*. Dr. DiPietro is Professor of Pediatric Radiology at the University of Michigan and is a member of the team that has been reviewing the head ultrasounds of the babies in the BEAM and BEARS for the past four years. Congratulations!

The answer is: Mr. Brown wears the black tie; Mr. Black wears the green tie and Mr. Green wears the brown tie.

## March 2005 Puzzler

Find a word that follows the first word in each clue and precedes the second, in each case making a fresh word or phrase. For example, the answer to *fish mix* might be *cake* making *fishcake* and *cake mix*, and the answer to *spider site* might be *web* making *spider web* and *website*.

1. first stream
2. high days
3. hot paddle
4. white bed
5. grand lode

6. break lane
7. blood room
8. bat friend
9. pick load
10. see mill

11. hung rig
12. gold bearer
13. tender cloth
14. six rat
15. miracle all

Be the first to email the correct answer to [Lucy\\_L@biostat.bsc.gwu.edu](mailto:Lucy_L@biostat.bsc.gwu.edu) for recognition in the June 2005 newsletter!

## Publications Committee Notices & Reminders

With the goal of making the results from the Network's research available to the public, the Publications Committee has worked very hard over the past year with Network investigators to determine, in particular, which secondary analyses (mostly from abstracts presented at professional meetings) were destined to become manuscripts and which were declared not feasible. To move the process along and lessen the backlog of partially finished analyses, specific policies were put into place. Those that are relevant to the submission process for SMFM and SGI abstract proposals are described below.

- Primary authors of manuscripts derived from presentations at SMFM 2004 and SGI 2004 are not eligible to have analysis requests move forward for SMFM 2006 unless a finished manuscript has been submitted, the manuscript has been declared not feasible, or other obstructions to completion exist.

- Primary authors of manuscript derived from SMFM 2005 and SGI 2005 must have submitted a draft manuscript or have declared the manuscript not feasible to have an analysis considered for SMFM 2006.

- Manuscripts resulting from presentations prior to SMFM 2005 are due by the October 2005 Steering Committee meeting. Manuscripts not completed by then, without good cause, will be moved to the inactive/archived list and will not receive BCC support after that without re-review by the protocol subcommittee and Publications Committee.

Network investigators should note that all completed Network studies are now open to analysis proposals from all investigators at all centers.

### MUFMU CALENDAR

#### Steering Committee Meetings

##### 2005

April 21-22  
July 21 - 22  
October 27 - 28

##### 2006

January 19 – 20  
April 27 – 28  
July 20 – 21  
October 19 - 20

#### Professional Meetings

<b>SMFM</b>	January 30-February 4, 2006, Miami, FL
<b>SGI</b>	March 22-25, 2006, Toronto, Canada

#### Publications Deadlines for SMFM 2006 Annual Meetings

Proposed SMFM abstracts to protocol subcommittee	March 31, 2005
Subcommittee prioritization completed	April 15, 2005
Publications Committee SMFM prioritization completed	May 1, 2005
Deadline for submission to SMFM 06	August, 2005
Manuscripts prior to SMFM 05 completed or archived	October 30, 2005
Deadline for SMFM 2006 manuscripts	December 15, 2005