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MACS news



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Overall Total: 47

Total this month: 10

An introduction and warm welcome to Kate Bassil who has joined MACS as the new Trial Coordinator. Kate's contact information appears on the masthead.

Welcome

Welkom

ברוכים הבאים

Bienvenido

Bienvenue

Meetings & Site Visits



Collaborators Meeting:

Plans are moving ahead for the April 26-28, 2002 meeting in Toronto with the confident hope that the current global tensions will have eased by then, making international travel reasonable once again. Invitations and a draft agenda will be mailed in the next few weeks.

Site Visits:

Kellie Murphy is planning a number of visits to interested and recruiting centres in Canada. We would be pleased to arrange for Kellie or another member of the Steering Committee to make a presentation in your hospital.

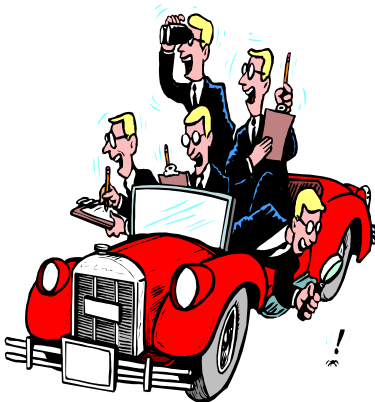
(Although we have put international travel on hold just for the moment, and have been forced to postpone our planned visit to Israel, we expect to undertake this and other such visits fairly early in the new year.)





Ethics Approvals

It hardly seems possible, but it is almost a year since we received the first local ethics approvals from participating centres. Under the International Conference of Harmonisation; Good Clinical Practice: (ICH/GCP) Consolidated Guideline each participating centre in a clinical trial like MACS is required to have their local ethics approval renewed annually and to provide us with a copy of that approval. We will notify each centre as their re-approval date approaches.



Data Form Notes

Where is... ??

The *Patient Contact Sheet* is an important document for recording contact information for MACS participants. Please be sure to collect and record the details for at least one secondary contact (in addition to the woman herself). This will be a big help in finding participants who move during the trial and will ensure that everyone is found for the follow-up. The most important secondary contact is usually the participating woman's mother. Remember to fax Side 1 of the sheet to us as a back-up for your local records.



Study drug labels

It is very important to apply the study drug labels to the data forms as a record that each patient has received her allocated study drug.

On the *Entry Form*, page 3 Item 36, apply the tear-off sticker from the outside of the study drug box.

On the *Treatment Form* (or *Offsite Treatment Form*) apply the stickers that are in each study drug packet for each dose of study drug that is given.



Recruitment

as of September 30, 2001

Annual Goal	Apr	May	Jun	Jul	Aug	Sep	Total
	01	01	01	01	01	01	

COUNTRY

(shaded area is prior to start-up)

CANADA	84	1	1	5	2	3	7	19
ISRAEL	93	3		2	1	4	2	12
USA	22	2	1	4				7
DENMARK	15	5				1	1	7
SWITZERLAND	5					2		2
Total	219	11	2	11	3	10	10	47

CENTRES BY COUNTRY

(shaded area is prior to start-up)

CANADA								
Children's & Women's, Vancouver	24		1	2		2		5
Mount Sinai, Toronto	23			2		1	2	5
Royal University, Saskatoon	13	1			1		4	6
CHUS (Fleurimont), Sherbrooke	10			1			1	2
Royal Alexandra, Edmonton	14				1			1

ISRAEL								
Ma'ayne Hayeshua, Bnei Brak	16	3		1				4
Rabin, Petach Tikva	26			1		2	2	5
Bnai Zion, Haifa	13				1	1		2
Soroka, Beer Sheva	38					1		1

USA								
Montefiore, Bronx	13	1	1	4				6
Albany Medical Center, Albany	9	1						1

DENMARK								
Aarhus University, Aarhus	15	5				1	1	7

SWITZERLAND								
CHU Vaudois, Lausanne	5					2		2

Centres awaiting first patient: [COUNTRY: Hospital, City (annual goal)] [month/year start-up package sent]

CANADA: Regina General, Regina (10) [07/01]. **ISRAEL:** Poriya Government, Tiberias (7) [05/01]; Meir, Kfar-Saba (18) [06/01]; Haemek, Afula (13) [07/01]. **USA:** Maricopa, Phoenix (11)[04/01]. **THE NETHERLANDS:** Atrium, Heerlen (6) [07/01].