PREVENT

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Investigator Newsletter

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REMICADECRD3001 — Phase IIIb – Crohn's disease

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RECRUITMENT UPDATES

As of 24th November 2011 we have 166 patients randomized and 245 patients screened!

- 77 active sites in North America have screened 94 patients and randomized 57 patients.
- 87 activated sites in Europe / Rest of World have screened 151 patients and randomized 109 patients.
- Fewer than 20 sites globally still to be activated

Soon we will have >180 active sites in 15 countries; please help us to get to the next goal of having 290 randomised patients!

Please keep your CRA and CMA informed of any potential patients at your site who may be eligible. Remember that patient enrolment is competitive and is not capped.

Medical Contacts

Don't forget that if you need to discuss a medical emergency with a PAREXEL physician outside of office hours you can contact the 24/7 Emergency Medical Hotline on +1-978-805-7613.

For protocol-specific questions you should continue to contact your local medical monitor during office hours:

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Required On-line Trainings

As noted in Memo No 001 sent to your site on 11Nov2011, in order to facilitate Good Clinical Practice (GCP) and Investigator Safety Training (IST), Janssen has made the following modules for interventional trials available:

- Good Clinical Practice (GCP) training is mandatory for the Principal Investigator (PI) and all staff listed on the **FDA-1572 form**. The GCP training module is optional for other site staff members.

  The Janssen GCP module is not required if acceptable external GCP training (as defined by Janssen) has been followed during the previous 3 years. A list of acceptable GCP training is available from your PAREXEL Clinical Research Associate (CRA) and Clinical Monitoring Associate (CMA).

- Investigator Safety Training (IST) is mandatory for all site staff performing activities such as detecting, reporting and clinical assessment of (serious) adverse events as documented on the **FDA-1572 form** and the Site Signature Log.

Your assigned CMA will request the email address for each person listed in Box 6 of the Form FDA 1572. Once that is provided, please be on the lookout for an email from **yourpartner@bracketglobal.com**. Please check your junk mail folders if you don't see the email. Your login information will be sent in two separate mails (one for username and one for password). Included in the email is the link to access the trainings.

This month's tips from COVANCE Labs:

- The lab manual is available on the dashboard—this is the quickest way to find the information you need about sample storage and shipment
- The labs will be closed at times during the Christmas holiday period—make sure to check the dates when you plan patient visits

Remember to ask your CRA/CMA if you have any questions or do not have access to any system.

COMING SOON

Continuing the Think Three campaign look out for...

- A vídeo from Dr Bob Diamond, discussing protocol amendment 4
- Further recruitment updates from the PREVENT team

Also look out for a new Spotlight on a Site feature in future newsletters

PHARMACY STAFF TIPS / REMINDERS

Confirmation of Drug Dosing:

In an attempt to avoid dosing errors, please be very careful to double check vial/ carton numbers before reconstituting study drug for an assigned dose.

Caution: Vial Labels contain Unblinded Information:

Be careful to ensure vial labels are not provided to blinded site staff — they contain unblinded information. Vial labels should be attached to the Drug Preparation Worksheet and retained only in the pharmacy files.

Storage TT4 sites:

For those sites using TT4s to monitor drug storage temperatures, please ensure you have at least 2 back up devices at all times. Additional TT4 devices can be ordered completing the *TT4 Supply Reorder Form* included in your Pharmacy Binder, and submitting it via email to CLS-ANS@parexel.com AND CLS-NA@parexel.com. Allow at least one week to receive your order - order in advance to ensure you have sufficient TT4s on site. Please remember to inform your IDM of TT4 reorders.

IVRS Confirmation receipts:

If you do not receive IVRS confirmations within 30 minutes of placing the call please contact Clinphone Support immediately. Support will be able to better address and resolve issues if they are notified at the time of the incident.

Temperature Monitoring:

Per *Temperature Monitoring Guidelines for Clinical Sites*, 15July2009:

Section 5.1.2: You must report a TOR in the event that the measured temperatures have exceeded the trigger levels for a reportable temperature excursion, i.e.:

- temperature of 1.4 degrees C or lower has been measured *or*
- temperature of 8.5 degrees C or higher has been measured.

Refer to your Temperature Monitoring Guidelines for additional guidance.

GCP Training:

The person acting as the lead Unblinded Pharmacist should be listed on the FDA form 1572. GCP training is mandatory for all individuals listed on the 1572. GCP training for all other unblinded pharmacy staff is optional. A GCP online training module is available. Please contact your IDM for access to the training module. The training module is not required if acceptable GCP training has been completed within the past 3 years. Your IDM can provide you with a list of acceptable GCP trainings.

REMEMBER: ONLY CONTACT IDM or IDM LEADS WITH ANY DRUG RELATED ISSUES OR QUESTIONS.