**Special Features**

**DOWG of the Month:**  
- Genitourinary

**CRSO Corner:**  
- Affiliate Updates  
- Nurse Triage  
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**CRCO Corner:**  
- PRMC Tips  
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- Tip of the Month:  
  - Regulatory Data Entry

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**Spring is on it’s way!**

And with it, brings the Spring *Wisconsin Oncology Network (WON)* Meeting on Saturday, April 21, 2012 at the Wisconsin Institute for Discovery (WID) on the UW-Madison Campus. We hope to see you there!

If you have questions about the conference, please contact the Affiliate Office at affiliatecoordinators@uwcarbone.wisc.edu

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**Clinical Research Offices Newsletter**

**Genitourinary DOWG**

**DOWG Leaders:** Glenn Liu, MD and David Jarrard, MD

**GU Oncology Physicians:**
- **Medical Oncologists:** George Wilding, MD; Douglas McNeel, MD; Justine Yang Bruce, MD; Jeremy Cetnar, MD; Josh Lang, MD; Glenn Liu, MD; **Urologists:** David Jarrard, MD; Jason Abel, MD; Tracy Downs; **Radiation Oncologist:** Mark Ritter, MD; **GU Pathologist:** Wei Huang, MD

**Program Manager:** Mary Jane Staab, RN,  
**Research Nurse Coordinators:** Dottie Horvath, RN, Jane Straus, RN, and Mulusew (Mulu) Yayehyirad, RN,  
**Research Specialists:** Janna Bergum, Kelly Simmons and Erica Orcholski

Mary Jane, Dottie and Jane have been part of the GU DOWG for over 10 years! Janna joined the group back in 2006, Jane in 2007, Erica in 2009, and Mulu was the most recent addition to the group in 2010. Their loyalty and dedication to the GU group has been a major factor in the continuing success of the GU DOWG.

This is an exciting time for the GU Group. In the last 5 years, GU has participated in multiple trials with therapies that have subsequently been approved or will soon be approved for the treatment of prostate or kidney cancer including: *provenge* - a vaccine immune therapy approved in 2010 for the treatment of metastatic hormone refractory prostate cancer and *abiraterone* - an antigen receptor directed therapy for treatment of metastatic hormone refractory prostate cancer post chemotherapy. *Axitinib* for renal cell cancer and *MDV3100* for prostate cancer are expected to be approved this year.

The GU DOWG is one of the initial members of the Prostate Cancer Clinical Trials Consortium (PCCTC), founded in 2006. PCCTC is a 13-member clinical research group sponsored by the Prostate Cancer Foundation and the Department of Defense Prostate Cancer Research Program. PCCTC members collaborate to design, implement and complete phase I and phase II trials in prostate cancer, rapidly bringing scientific discoveries to patients. Each member is expected to present 2 new studies to the consortium each year, and participation in the PCCTC has provided the UWCCC GU DOWG access to a wide range of trials and the opportunity to work with other major prostate cancer centers. Of the 19 studies open to enrollment in the GU Group, nine are PCCTC trials.

The GU DOWG is involved with a variety of exciting investigator-initiated trials. GU has 2 active trials involving a vaccine developed by Dr. Douglas McNeel:  
- Multicenter trial COO8801: *Randomized Phase II Trial of a DNA Vaccine Encoding Prostatic Acid Phosphatase (pTVP-HP) versus GM-CSF Adjuvant in Patients with Non-Metastatic Prostate Cancer* and single center trial COO8802: *A Pilot Randomized Two-Arm Study of a DNA Vaccine Encoding Prostatic Acid Phosphatase (PAP) in Patients with Non-Metastatic Castrate-Resistant Prostate Cancer*. GU is also coordinating a multicenter imaging trial of Dr.’s Glenn Liu and Robert Jerai:  
  - **CO11811:** *NaF PET/CT repeatability, responsiveness, and response assessment in patients with metastatic castrate-resistant prostate cancer to bone treated with either docetaxel-based chemotherapy or androgen receptor (AR) – directed therapies*. They hope that the NaF PET/CT will improve the ability to assess bone metastasis response to treatment in patients with metastatic prostate cancer. They recently activated a quality of life study developed by Jane Straus, RN with the assistance of Drs. Justine Bruce and Michael Harrison. The trial is comparing quality of life outcomes for two agents used to treat hot flashes in men with prostate cancer who are receiving hormone therapy.
**Affiliate Corner**

**Wisconsin Oncology Network (WON) FAQs**

**Q: Do WON sites use the UW-IRB approved consent document(s)?**

**A:** No, the WON sites need to modify the UW-IRB approved consent template(s) to include their local information, such as: site name, local contact information, site PI, etc. For this reason, we ask that the DOWG send the Word versions of the consenting documents to the affiliate office for distribution to the sites in addition to uploading the .pdf versions into OnCore.

**Q: How is drug distribution handled for WON sites?**

**A:** Drugs are shipped to individual WON sites by the UWHC Pharmaceutical Research Center (PRC) or by the sponsor. Refrigerated drug however, cannot be shipped by the PRC and needs to be shipped directly to WON sites from the sponsor.

**Q: How are protocol amendments, revised consents, updated IDBs or local SAEs distributed to the WON sites?**

**A:** The Affiliate Office sends out a weekly WON protocol update email that lists any new study information. The information is also reviewed and discussed at the monthly WON conference call.

**Q: How are the WON sites paid for their participation?**

**A:** The Affiliate Office works with UW Research & Sponsored Programs (RSP) to initiate sub-contracts with sites that are participating in a particular WON protocol. Once the sub-contracts are executed, the Affiliate Office helps sites prepare and submit invoices through the UW system for payment. The Affiliate Office reviews charges with the appropriate PM prior to submitting. In addition, the Affiliate Office invoices the DOWG for CRO-related charges on a yearly basis.

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**Helpful Information About Health Link**

Policies related to the Health Link system can be useful for answering questions from sponsors about access, quality assurance, and audit trails. Health Link policies are found on UConnect (https://uconnect.wisc.edu) by navigating in the orange tool bar at the top of the page and clicking on the Policies button. Remember that UW Health Policies are for internal use only. A few helpful policies include:

- UWHC P&P 6.25 "Health Information Management Procedure for Verification of Record Entries & Author Identification"
- UWHC P&P 4.39 "Electronic Medical Record Audit Policy"
- UWHC P&P 6.15 "Medical Record Documentation"
- UWHC P&P 1.02 "Access to Electronic Information Systems"
With the changing of the season, comes change in the CRO. **Mary Beth Wims**, Affiliate Coordinator, will be leaving the CRO for South Korea where she will be teaching English to middle-school aged children. In addition, **Lynn Volk** will be leaving the CRO for a Data Manager position in the Lymphoma DOWG. We wish them both the best of luck in their endeavors and they will be sorely missed.

**Protocol Review & Monitoring**

**Tips of the Month**

1. PRMC has updated the following forms:
   - New Protocol Number Request Form
   - ePRMS Submission Short Form for Initial Review
   Please discard the old forms and use the new forms on the UWCCC website
2. Please do not request a **protocol status change** until the date of the request has occurred, as it is not possible to enter a future date in OnCore.
3. Remember to use the Protocol Status Change Request Form when requesting a protocol status change. The information required for processing the change is found only on this form.
4. IRB Exempt protocols are expected to be closed with the IRB. When an IRB exempt study is completed, please remember to close it at the IRB and submit a Protocol Status Change Request to the PRMC Coordinator to Terminate the study in OnCore.

**Looking up CITI Certification:**

You can verify CITI training for yourself or your staff by going to the following website: [https://my.gradsch.wisc.edu/lookups/citi/trainingStatus.html](https://my.gradsch.wisc.edu/lookups/citi/trainingStatus.html)

Log in with your NetID and Password. In the Search box, enter the Last Name of the person you need to verify. DO NOT hit Enter, or else it will not give you the names! A list of names will appear in a drop down and you will be able to select the intended person. Please note: HIPAA has been a recent addition to this look-up function, so that you may not be able to find everyone’s HIPAA in this location.
OnCore Tips of the Month

Do you get too many emails? Of course you do!
The Data Field Definitions (DFDs) detail the UWCCC requirements for how data must be entered in OnCore. Get fewer queries in your inbox from the OnCore Support Team by utilizing the DFDs when entering information into the database. On the OnCore database main page, you will find all the DFDs for all the different consoles in the database. Please refer to them when entering data into OnCore.....you will be pleasantly surprised by the reduction of queries you will receive when you follow the DFDs!

CORRECTION
In last month’s CRO newsletter, we incorrectly indicated that the upcoming ECOG Audit was scheduled for April 9-11. The correct dates for the UWCCC ECOG audit UWCCC is May 9-11, 2012.

Sorry for any confusion!

OnCore Support Corner

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OnCore Database

Regulatory Data Entry Tip:
Some studies that are entered into OnCore are UW-IRB exempt. OnCore requires an IRB approval status to open a study to accrual in the database, however, OnCore currently does not have an “exempt” status. In order to enter an IRB exempt status into OnCore, see below:

In the PC Console > Reviews Tab > IRB Action History > New IRB Record
1. Submit Date: Date submitted to the IRB
2. Review Date: Date the IRB assigned the “Exempt” status.
3. IRB Committee: IRB that assigned the “Exempt” status.
4. Review Reason: Initial Review
5. Review Type: Expedited
6. Action: Approved
7. Expiration Date: Leave blank.
8. Summary: “IRB Exempt” is noted.
9. Add Details: Any applicable documents are entered here.

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OOPS!