

YOUR MAPRIUPDATE Mid-Atlantic Permanente Research Institute

EXECUTIVE DIRECTORS UPDATE

Dear Colleague,

MAPRI has had a tremendous 2011 and looking forward to an even greater 2012! As you are probably aware, The Mid-Atlantic Permanente Research Institute (MAPRI) of MAPMG, in collaboration with KPMAS, is the research core for MAPMG and KPMAS, performing high quality research for a world class medical care program. We increased our



capacity and production in areas of health services and disparities research, research data capacity and health informatics research, clinically and research relevant registries, oncology epidemiology, and clinical trials. Since January, 2011, we have published and presented 11 manuscripts and abstracts as first author, and an additional 23 as co-authors. We presently have 46 active studies.

MAPRI is expanding and further developing our clinical trials program for KPMAS. Many clinical trials are needed for our members to have access to the highest quality healthcare, as well as the knowledge gained for medicine generally. With the Affordable Care Act (healthcare reform), we anticipate expanded access to clinical trials. To meet that capacity, our program capacity grew in 2011 to six clinical research nurses, two research assistants, and extensive administrative support. We increased the number of clinical trials we offer our members, including new membership in National Cancer Institute sponsored cancer clinical trials collaborative. We have ongoing trials in the areas of hepatitis C, heart failure, and oncology.

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This past year we developed new mission and vision statements to better reflect our commitments to MAPMG clinical research, serve the needs of our clinicians and our members, and a continued emphasis on ethical and compliant research. To best achieve this vision, MAPMG and MAPRI hired three new research scientists (in the areas of health disparities, health services and policy, and oncology epidemiology), and anticipate programmatic expansion in the areas of women's health, cardiovascular (heart failure), and health systems research. We expanded these and other established research programs, as well as increasing our grants and studies administration capacity, which further helps our program's development.

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In 2011, MAPRI increased its collaborations with research entities outside of KP, including being accepted as member of HMO Research Network and an active member of Cancer Research Network. We also increased our interregional research collaborations, including the Center for Effectiveness and Safety Research. Within our region, MAPRI created the Clinician Research Committee, to greatly facilitate clinician initiated research studies. We also assisted resident and KPMAS-employee initiated research. MAPRI staff development and growth is critical to increased capacity to ensure these successful collaborations and clinician researcher satisfaction.

"Essential to our success, is your MAPRI.

We are most grateful to the internal and external funding received in order to achieve all of these accomplishments. We are especially grateful to KPMAS Community Benefits Program (CB) for its ongoing support, as well as MAPMG support. External supengagement in port (NIH, CESR, and other institutions) also helped us achieve our goals for 2011. Our full annual report is available at our new MAPRI website (see related article in this newsletter) at http://mapri.kaiserpermanente.org/564/2011-mapri-annualreportwith-an-eye-to-2012/

In 2012, MAPRI anticipates continued deliberate and strategic growth. We look forward to continued internal and external financial support. We will continue to honor our mission to address the clinical, health policy, and service questions perplexing MAPMG providers, our medical program, and the healthcare system, through which we aim to improve the care experience of our patients and communities we serve. But essential to our success, is your engagement in MAPRI. Please feel free to send me your study ideas, thoughts on how we can improve our service, and topic areas we should explore. We are here for you. Help us succeed even more.

With Gratitude, Michael





P.S. Always feel free to contact me, either by Lotus Notes (Michael Horberg) or by phone at 301-816-6302. I truly want to hear from you! MAPRI is here to give our providers the best research possible, so we can give our members the finest healthcare possible.

WELCOME THE NEW MANAGING DIRECTOR



MAPRI is very excited to have our new Managing Director for Research, Tom Dang, who started with us in early February. He brings a wealth of knowledge and experience in the area of research administration. Before joining MAPRI, he worked at the Henry M. Jackson Foundation for the Advancement of Military Medicine as the Director of Operations & Finance for the Department of Defense's Infectious Disease Clinical Research Program based at Uniformed Services University in Bethesda, MD.

There he managed all operations and financial aspects of a multimillion dollar, multi-site, international, clinical research program.

He also has worked at the National Rehabilitation Hospital, part of the MedStar Health System, for over 13 years. He received his Bachelor's and Master's degrees in Biomedical Engineering from the Catholic University of America in Washington, DC. In his spare time, he enjoys mountain and road cycling, skiing and travelling.

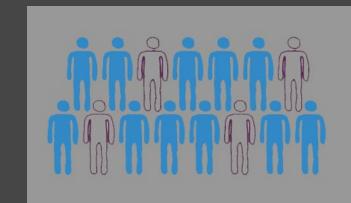
KPMAS Celebrated the 4th Annual Research Participants Week

April 15 - 21, 2012

4th Annual

One of the core principles of human research at KP is that we do not compromise our obligation to keep our members' health and well-being foremost. We also know that our clinical trials research program could not have been possible without the participation of our members. The Mid-Atlantic States region currently has 129 members par-

ticipating in clinical trials. During the 4th Annual Research Participants appreciation week (which is sponsored by our region's Institutional Review Board or "IRB"), the research community reached out to express gratitude to those research participants for their time and commitment. As has become tradition, we use this week in April to recognize the essential role our members as research participants have to the success of our clinical research program.





MAPRI WEBSITE

Kaiser Permanente's Mid-Atlantic Permanente Research Institute is proud to announce the launch of our brand new dedicated research website. You can find the latest breaking MAPRI news, articles, publications, contact information and much more at

http://mapri.kaiserpermanente.org

The PEAL Network

The burden of asthma falls most heavily on our nation's vulnerable groups, including children, racial/ethnic minorities, and the poor. Yet, these groups have been underrepresented in existing research, and there is a dearth of evidence to guide many common clinical decisions, such as asthma drug use in children. The Population-Based Effectiveness in Asthma and



Lung Diseases (PEAL) Network seeks to fill these gaps and to accelerate comparative effectiveness research in asthma and lung diseases by combining the rich data and scientific resources of four large health plan populations and one state Medicaid population.

The PEAL Network links over seven years of patient-level data on diagnoses, utilization, prescription drug use, costs, and sociodemographic characteristics of patients with asthma, and other chronic lung diseases, such as chronic obstructive pulmonary disease, chronic bronchitis, and cystic fibrosis. The PEAL Network includes nearly two million person-years of data on patients with asthma, alone. Using this data, we are in the process of conducting various analyses to assess the comparative effectiveness of major asthma controller drug regimens in real-world settings. This includes a detailed examination of patient adherence to various drug regimens and the extent to which modifiable barriers to adherence contribute to adverse asthma outcomes. Dr. Vicki Fung serves as a site principal investigator on the study and contributes her expertise in pharmaceutical policy research, clinical economics, and observational data analyses to the main study. She will also lead an upcoming analysis to investigate the effects of benefit design on asthma drug use and clinical outcomes. This large, diverse network provides a model for comparative effectiveness research in chronic diseases and vulnerable populations, and ad-

Research Scientist Profiles



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Chu-Ling Yu, ScD,

Chu-Ling Yu, ScD, joined MAPRI in September 2011 as a Research Scientist in Oncology Epidemiology. One of Chu-Ling's main research interests lies in treatment-related adverse health outcomes among cancer survivors. Her previous research in this area focused primarily on radiotherapy-related subsequent primary cancers in long-term childhood cancer survivors. For example, in an article published on the *Journal of the National Cancer Institute*, Chu-Ling and colleagues studied the cause-specific mortality in a cohort of long-term survivors of retinoblastoma (RB), a race childhood cancer of the eyes. Survivors of hereditary RB (defined in the study as bilateral RB and unilateral RB survivors with a positive family history of RB) are known to be at markedly increased risk of dying from a subsequent primary cancer, especially if they had received radiotherapy for RB.

Bridget Gaglio, PhD,



Bridget Gaglio, PhD, joined MAPRI from Kaiser Permanente Colorado in the fall of 2011 as a Research Scientist focusing on health disparities.

Her work includes conducting research studies focused on three main themes:

 descriptive and intervention research studies grounded in theory and conducted in real world settings that demonstrate effectiveness of strategies to

- reduce well-documented racial/ethnic health inequalities in health care access and utilization,
- 2) health communication interventions specifically focusing on assuring access to information for individuals varying in health literacy and numeracy abilities, and
- 3) dissemination and implementation of best practices.

Bridget is the principal investigator of two studies examining communication of cancer-related information among diverse populations and in multiple languages. In addition, Bridget is conducting two formative evaluation projects focused on communication of information during cancer care that will provide a foundation for planned future proposals that will develop, test, and implement best practices in cancer communication with diverse patient populations in multiple healthcare delivery systems and to evaluate the impact of such best practice.

Bridget received her training at The University of Texas School of Public Health (masters) in epidemiology and at the University of Colorado (PhD) in health and behavioral sciences. Outside of work, Bridget is an avid runner and triathlete.

If you would like to communicate directly with Bridget Gaglio, she can be reached at: (301) 816.5796 or email at Bridget.Gaglio@kp.org.

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However, mortality information is still limited among long-term hereditary RB survivors who received radiotherapy. Based on data from a cohort of 1854 RB survivors (1092 hereditary and 762 nonhereditary) diagnosed between 1914 and 1996, Chu-Ling and colleagues reported that, compared to the general population, excess mortality from subsequent primary cancers in hereditary RB survivors extended beyond 40 years, By contrast, there was no evidence of excess mortality from non-cancer causes among nonhereditary patients compared with the general population.

At MAPRI, Chu-Ling currently leads the development of the Virtual Tumor Registry of the KPMAS population. The registry will serve as a resource not only for cancer research projects within KPMAS, but also for external collaborations. She is also expanding her research efforts in cancer survivorship research by studying other serious treatment-related health outcomes in adult cancer survivors. In addition, Chu-Ling will serve as the Site Principal Investigator of the Cancer Research Network, a large national collaborative research effort involving many other KP regions, which is currently under scientific review at the National Cancer Institute. She will also collaborate with Dr. Michael Horberg on a multi-site study on HIV care.

Chu-Ling received her training at the National Taiwan University (BS), Yale University (MPH), and Harvard University School of Public Health (ScD). She also completed a post-doctoral fellowship at the National Cancer Institute's Division of Cancer Epidemiology and Genetics. In her spare time, Chu-Ling is a photography enthusiast and enjoys visiting museums and art galleries. If you would like to communicate directly with Chu-Ling, she can be reached at: (301) 816.5923 or email at Chu-Ling.x.Yu@kp.org

MAPRI Research Published & Presented

MAPRI has been making an impact on medical research in the United States. Listed below are our recent publications and meeting abstracts presented.

MANUSCRIPTS

- **1.** Bredfeldt CE, Compton-Phillips AL, Snyder MH. Effects of between visit physician-patient communication on Diabetes Recognition Program scores. *Int J Qual Health Care.* Dec 2011;23(6):664-673.
- 2. Horberg M, Hurley L, Towner W, Allerton M, Tang B, Catz S, Silverberg M, Quesenberry C. Determination of Optimized Multidisciplinary Care Team for Maximal Antiretroviral Therapy Adherence. *JAIDS*. In press.
- **3.** Abraham AG, Lau B, Deeks S, Moore RD, Zhang J, Eron J, Harrigan R, Gill MJ, Kitahata M, Klein M, Napravnik S, Rachlis A, Rodriguez B, Rourke S, Benson C, Bosch R, Collier A, Gebo K, Goedert J, Hogg R, **Horberg M**, Jacobson L, Justice A, Kirk G, Martin J, McKaig R, Silverberg M, Sterling T, Thorne J, Willig J, Gange SJ. Missing data on the estimation of the prevalence of accumulated human immunodeficiency virus drug resistance in patients treated with antiretroviral drugs in North America. *Am J Epidemiol.* Sep 15 2011;174(6):727-735.
- **4.** Breyer BN, Van den Eeden SK, **Horberg MA**, Eisenberg ML, Deng DY, Smith JF, Shindel AW. **HIV** status is an independent risk factor for reporting lower urinary tract symptoms. *J Urol.* May 2011;185(5):1710-1715.
- **5.** Chao C, Xu L, Abrams DI, Towner WJ, Horberg MA, Leyden WA, Silverberg MJ. HMG-CoA reductase inhibitors (statins) use and risk of non-Hodgkin lymphoma in HIV-positive persons. *AIDS*. Sep 10 2011;25(14):1771-1777.
- **6.** Gallant JE, Adimora AA, Carmichael JK, **Horberg M**, Kitahata M, Quinlivan EB, Raper JL, Selwyn P, Williams SB. **Essential components of effective** HIV care: a policy paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. *Clin Infect Dis.* Dec 2011;53(11):1043-1050.
- 7. Glasgow RE, Gaglio B, Bennett G, Jerome GJ, Yeh HC, Sarwer DB, Appel L, Colditz G, Wadden TA, Wells B. Applying the PRECIS Criteria to Describe Three Effectiveness Trials of Weight Loss in Obese Patients with Comorbid Conditions. *Health Serv Res.* Nov 2 In press.
- 8. Kleinerman RA, Yu CL, Little MP, Li Y, Abramson DH, Seddon JM, Tucker MA. Variation of second cancer risk by family history of retinoblastoma among long-term survivors. *J Clin Oncol*. Mar 20 2012;30(9):950-957.
- **9.** Mazor KM, Roblin DW, Williams AE, Greene SM, **Gaglio B**, Field TS, Costanza ME, Han PK, Saccoccio L, Calvi J, Cove E, Cowan R. **Health literacy and** cancer prevention: Two new instruments to assess comprehension. *Patient Educ Couns*. In press.
- **10.** Meunier S, Russmann H, Shamim E, Lamy J, Hallett M. Plasticity of cortical inhibition in dystonia is impaired after motor learning and Paired-Associative Stimulation. *Eur J Neurosci.* Mar 2012;35(6):975-986.
- 11. Neta G, Yu C, Brenner A, Gu F, Hutchinson A, Pfeiffer R, Sturgis E, Xu L, Linet S, Alexander B, Chanock S, A.J. S. Common Genetic Variants in the 8q24 Region and Risk of Papillary Thyroid Cancer. *Laryngoscope*. Jan 24 2012 [Epub ahead of print].
- **12.** Potter MB, Somkin CP, Ackerson LM, Gomez V, Dao T, Horberg MA, Walsh JM. The FLU-FIT program: an effective colorectal cancer screening program for high volume flu shot clinics. *Am J Manag Care*. 2011;17(8):577-583.
- **13.** Reed M, Graetz I, Wang H, Fung V, Newhouse JP, Hsu J. Consumer-directed Health Plans With Health Savings Accounts: Whose Skin is in the Game and How do Costs Affect Care Seeking? *Med Care*. Feb 8 2012 [Epub ahead of print].
- **14.**Schwarz EB, Postlethwaite D, Hung YY, Lantzman E, Armstrong MA, **Horberg MA**. Provision of Contraceptive Services to Women with Diabetes Mellitus. *J Gen Intern Med*. Sep 16 2011:[Epub ahead of print].
- **15.** Shindel AW, Horberg MA, Smith JF, Breyer BN. Sexual dysfunction, HIV, and AIDS in men who have sex with men. *AIDS Patient Care STDS*. Jun 2011;25(6):341-349.
- **16.** Silverberg MJ, Chao C, Leyden WA, Xu L, **Horberg MA**, Klein D, Towner WJ, Dubrow R, Quesenberry CP, Jr., Neugebauer RS, Abrams DI. **HIV** infection, immunodeficiency, viral replication, and the risk of cancer. *Cancer Epidemiol Biomarkers Prev* Dec 2011 20(12):2551-2559. [Epub ahead of print].
- 17. Sterling TR, Lau B, Zhang J, Freeman A, Bosch RJ, Brooks JT, Deeks SG, French A, Gange S, Gebo KA, John Gill M, Horberg MA, Jacobson LP, Kirk GD, Kitahata MM, Klein MB, Martin JN, Rodriguez B, Silverberg MJ, Willig JH, Eron JJ, Goedert JJ, Hogg RS, Justice AC, McKaig RG, Napravnik S, Thorne J, Moore RD. Risk factors for tuberculosis after highly active antiretroviral therapy initiation in the United States and Canada: implications for tuberculosis screening. *J Infect Dis.* Sep 15 2011;204(6):893-901.

ABSTRACTS

- 1. Bredfeldt CE, McFarland L. Considerations in the design and use of an oracle-based virtual data warehouse *Clin Med Res.* November 2011;9(3-4):185-186.
- 2. Bredfeldt CE, Rowe M, Compton-Phillips AL, Snyder MH. Secure messaging effect on health outcomes for diabetic patients. *AMIA Annu Symp Proc.* November 2009.
- **3. Fung V**, Price M, Busch AB, Landrum MB, Nierenberg A, Dow W, Fireman B, Hui R, Frank R, Newhouse J, Hsu J. **Medicare Part D** Cost-sharing and Antipsychotic Drug Use Among Beneficiaries with Schizophrenia. *American Society for Health Economists, Biennial Meeting*.; June 2012 (Accepted).
- **4. Fung V**, Price M, Huang J, Brand RJ, Dow W, Newhouse JP, Hsu J. Drug Coverage for Low Income Medicare Beneficiaries: How Do Low Income Cost-Sharing Subsidies Affect Patient Behaviors? *AcademyHealth Annual Research Meeting*. Seattle; June 2011.
- **5. Gaglio B**, Rabin BA, Shoup JA, Narwaney K, Mazor K, Milberg P, Street R. Information seeking behavior among cancer patients of an integrated healthcare delivery system: What is needed and in what format? *HMORN Annual Conference* Seattle, WA; April 2012
- **6. Gaglio B**, Arora N, Boggs J, Lemay C, Firneno C, Mazor K. Assessing communication during cancer care: Multiple perspectives, multiple considerations. *HMORN Annual Conference* Seattle, WA; April 2012
- 7. Horberg. M, Hurley. L, Klein. D, Silverberg. M, Quesenberry. C, Mugavero. M. Early Missed Office Visits Post-HIV Diagnosis and Mortality in a Large Healthcare System. 19th Conference on Retroviruses & Opportunistic Infections; March 2012
- **8.** Horberg M, Hurley L, Towner W, Gambatese R, Klein D, Antoniskis D, Weinberg W, Kadlecik P, Kovach D, Mogyoros M, Remmers C, Quesenberry C, Silverberg M, Johnson M. HIV quality metrics: Association between retention in care and maximal viral control. 49th Annual Meeting of the Infectious Diseases Society of America; October 2011.
- **9. Horberg M**, Hurley L, Towner W, Allerton M, Tang B, Catz S, Silverberg M, Quesenberry C. Determination of optimal multidisciplinary care teams (MDCT) for achieving HIV RNA below limits of quantification. *6th International Conference on HIV Treatment & Prevention Adherence* July 2011.
- **10.** Delorenze G, **Horberg M**, Silverberg M, Tsai A-L, Quesenberry C. Time Trends in Methicillin-resistant staphylococcus aureus (MRSA) Infection Rates Comparing HIV-infected Patients with the General (HIV-uninfected) Patient Population. *19th Conference on Retroviruses and Opportunistic Infections*; March 2012
- 11. Graetz I, Fung V, Hsu J, Reed M. COBRA ARRA Subsidies: Limits of a Carrot-Only Strategy. *AcademyHealth Annual Research Meeting*. Seattle; June 2011.
- **12.** Hanna D, Gebo K, Hessol N, **Horberg M**, Kirk G, Kitahata M, Napravnik S, Sterling T, Willig J, Gange S. Disparities in Rates of HIV treatment Initiation & Viral Load Suppression across US States, 2001-2007. NA-ACCORD, trans. *19th Conference on Retroviruses and Opportunistic Infections*; March 2012
- 13. Hannsen C, Desai S, Cheetham C, Li DK, Raebel M, Glanz J, **Bredfeldt C**. H1N1 flu and pregnancy: the Kaiser Permanente Experience. *Clin Med Res*. November 2011;9(3-4):155.
- **14.** Hsu J, Price M, **Fung V**, Dow W, Newhouse J. Non-linear Cost-sharing & Projected Drug Burden: Adherence to Chronic Drug Regimens in the Medicare Part D Program. *American Society for Health Economists, Biennial Meeting;* June 2012 (Accepted).
- **15.** Hsu J, Huang J, **Fung V**, Brand R, Bertko J, Newhouse J. Private Plans in Medicare: locking the Revolving Door". *AcademyHealth Annual Research Meeting*. Seattle; June 2011.
- **16.** Huang J, **Fung V**, Bertko J, Newhouse J, Hsu J. Medicare Advantage Enrollees: Legacies and Newcomers, Who Art Thou? *AcademyHealth Annual Research Meeting*. Seattle; June 2011.
- **17.** Klein D, Leyden W, Xu L, Chao C, **Horberg M**, Towner W, Hurley L, Quesenberry C, Silverberg M. Contribution of Immunodeficiency to Coronary Heart Disease: Cohort Study of HIV-infected and HIV-uninfected Kaiser Permanente Members. *Epidemiology & Prevention/Nutrition, Physical Activity, & Metabolism 2012 Scientific Sessions*; March 2012
- **18.** Silverberg M, Chao C, Leyden W, Xu L, Yu J, **Horberg M**, Klein D, Towner W, Quesenberry C, Abrams D. Cancer Stage, Age at Diagnosis & Survival Comparing HIV+ & HIV- Individuals w/ Common Non-AIDS-Defining Cancers. *Conference on Retroviruses & Opportunistic Infections*; March 2012
- **19.** Towner W, Leyden W, Chao C, Xu L, **Horberg M**, Klein D, Tang B, Hurley L, Silverberg M. **Rhabdomyolysis in HIV-infected versus** HIV-uninfected Persons Enrolled in Kaiser Permanente California. *41st Annual Meeting of the Infectious Disease Society of America*; October 2011.

KPMAS ONGOING CLINICAL TRIALS

STUDY TITLE	PI	FOR MORE INFO CONTACT
A Phase III, open label studyof once daily BI 201335 240mg for 24 weeks in combination with pegylated interferon-a (PegIFN) and ribavirin (RBV) in patients with genotype 1 chronic hepatitis C infection who failed a prior PegIFN/RBV treatment	Robert W. Sjogren, MD	<u>Linda Steeby</u> (703) 922-1310
A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer (NSABP B-47)	Leon Hwang , MD	<u>Diane Fisher</u> (240) 632-4284
Statin Polyp Prevention Trial in Patients with Resected Colon Cancer (NSABP P-5)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
Phase III Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2-Positive Ductal Carcinoma in Situ Resected by Lumpectomy (NSABP B-43)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed following Carboplatin, Paclitaxel and Bevacizizumab for Advanced Non-Squamous NSCLC (ECOG E5508)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
A Randomized, Phase III Study of Standard Dosing versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer, For Patients with Bone Metastases from Breast Cancer, Prostate Cancer or Multiple Myeloma (CALGB 70604)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX plus CELECOXIB or PLACEBO for Patients with Resected Stage III Colon Cancer. (CALGB/SWOG 80702)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
A Randomized study to prevent Lymphedema in Women Treated for Breast Cancer – Education only (CALGB 70305)	Amadea Tette, MD	<u>Diane Fisher</u> (240) 632-4284
Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone AnTagonist. (CLOSED TO ENROLLMENT)	Priti K. Sood, MD	<u>Aundria Cosby</u> (301) 618-5941
Long-Term Follow-Up of Subjects in a Phase 1,2 or 3 Clinical Trial in which Boceprevir or Narlaprevir was Administered for the Treatment of Chronic Hepatitis C. (CLOSED TO ENROLLMENT)	Robert W. Sjogren, MD	<u>Velga Brolis</u> (703) 531-1661
A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Early vs Standard Zoledronic Acid to Prevent Skeletal Related Events in Men with Prostate Cancer Metastatic to the Bone (CALGB 90202) (CLOSED TO ENROLLMENT)	Leon Hwang, MD	<u>Diane Fisher</u> (240) 632-4284
A Phase III, Randomised, Double-Blind and Placebo-Controlled Study of Once Daily BI201335 120 mg for 24 Weeks and BI 201335 240 mg for 12 Weeks in Combination with Pegylated Interferon-Alpha and Ribavirin in Treatment-Naive Patients with Genotype 1 Hepatitis C Infection (CLOSED TO ENROLLMENT)	Robert W. Sjogren, MD	<u>Linda Steeby</u> (703) 922-1310