

METASTATIC OOPHORECTOMY AND TAMOXIFEN STUDY NEWS

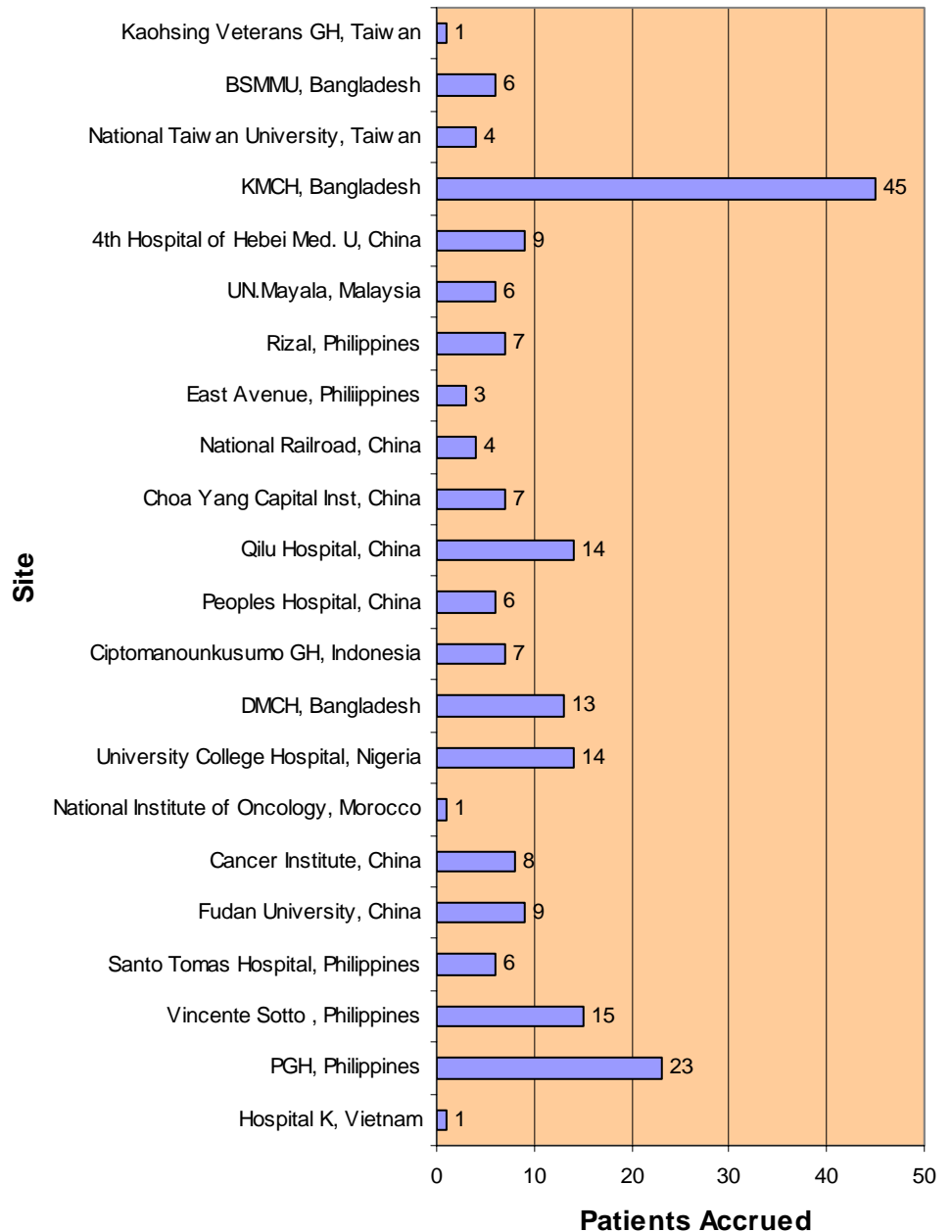
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ENROLLMENT BY SITE, DECEMBER 31, 2009

To date we have reached **60% of our accrual goal of 350 patients**. All active sites should continue to enroll patients on a regular basis. We hope to see improved enrollment in the New Year!



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A Comprehensive Cancer Center Designated by the National Cancer Institute



DATA SAFETY AND MONITORING COMMITTEE RESULTS

As you know, this study has an international, multi-disciplinary data safety and monitoring committee which meets on an annual basis. The role of this committee is to monitor study activities and ensure that the treatment we provide continues to be appropriate for our study patients. Committee members look at our accrual numbers, adverse events, and other aspects of the study in order to recommend whether the study should continue.

This year the Committee met on November 30, 2009. After a careful review, the Committee felt that the study was progressing well and that the treatment

provided is effective. Furthermore, the Committee felt that the study will be able to answer the questions raised by the protocol and that accrual will continue sufficiently to meet the stated accrual goals. The study will continue as planned.

Congratulations to all our sites for your work to support study goals!

IN APPRECIATION

In September the Ohio State University study team met to discuss study accrual and provide recommendations about how to proceed. Upon examination of the accrual trends of various sites, it was decided that some sites have completed accrual while others will continue to enroll new patients. As of the end of September, the following sites were closed: Kushtia General Hospital, Bangladesh; National Cancer Institute, Bangladesh; Santo Tomas, Philippines; Hospital

K, Vietnam; E. Avenue, Philippines; All China sites with the exception of Fudan; National Institute of Oncology, Morocco; and Dr. Ciptomanouksumo General Hospital, Indonesia. Sites that are no longer adding patients should continue to follow up with patients and ensure blood samples are shipped to the US. Many thanks to these sites for their contributions—women around the world will be the beneficiaries!

MEMO TO INVESTIGATORS FROM DR. LOVE

TIMING OF PRIMARY TUMOR SURGERY

As you will recall, we have encouraged thinking about study eligible and participating patients having primary tumor surgery if their tumors are technically resectable. As the study has gone on many such patients have had mastectomies at the same anesthesia time—at on study—as they have had their oophorectomies. Regrettably it has been our experience that these patients often experience acceleration in the growth of their metastatic disease, which process is not controlled by the oophorectomy/tamoxifen treatment. In contrast patients, who are treated with oophorectomy/tamoxifen alone, and then go on to have a partial response in their primary tumor site with shrinkage and scarring of this tumor, these patients

who have primary tumor surgery seem to do well. Thus at this time our advice is that primary tumor surgery should be delayed if at all possible in study patients. If some local treatment is absolutely necessary, radiation therapy, if available, appears to be a better option.

Richard R. Love, M.D.

Principal Investigator

REFRESHER: WHEN TO REPORT ADVERSE EVENTS

There has been some confusion about what is considered an adverse event and when to report them. Only **serious adverse events** should be reported within 24 hours of the event.

An adverse event is considered serious if it meets one of the following criteria:

- It results in death. Therefore any death that occurs should be reported as an adverse event.
- It placed the patient at immediate risk of death.
- It requires or prolongs inpatient hospitalization (requires at least a 24 hour inpatient hospitalization, or prolongs a hospitalization beyond the expected length of stay).
- It is disabling (results in a substantial disruption of the patient's ability to carry out normal life functions).
- It does not meet any of the above criteria, but could jeopardize the patient and might require medical or surgical intervention to prevent one of the outcomes listed above.

When serious adverse events occur, please report them within 24 hours by completing the online adverse event form. Events such as patients moving abroad or deciding to stop taking Tamoxifen for chemotherapy are not considered adverse events. These types of events need to be noted on the follow up form only.

SITE PHOTOS



Renewing our partnership in Bangladesh at a contract signing ceremony in Dhaka. From left to right, Rashed Ahmed, Reza Salim, Dr. Richard Love, and Heather Roberto



Heather Roberto meets with our newest research coordinator, Kuei-Chih Tien ("Candy"), at Kaohsiung Veterans General Hospital in Kaohsiung, Taiwan in June 2009.



Dorsia Wakawa and Linda McCart (front row) with the PGH team hard at work during October site visit to Manila, Philippines

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Check out the www.ibcrf.org website!

We would appreciate any news, patient success stories, pictures or suggestions for our next newsletter.

Please e-mail Heather.Roberto@osumc.edu

R E S E A R C H . . . F I N D I N G A N S W E R S F O R W O M E N
E V E R Y W H E R E

ACTIVE STUDY SITES AS OF JANUARY 2010

Bangladesh

- Dhaka Medical College and Hospital, Dhaka
- BangaBandhu Sheikh Mujib Medical University, Dhaka
- Japan Bangladesh Friendship Hospital, Dhaka
- Khulna Medical College Hospital, Khulna

Nigeria

- University College Hospital, Ibadan

China

- Fudan University Cancer Center, Shanghai

Malaysia

- University of Malaya Medical Center, Kuala Lumpur

Philippines

- Philippines General Hospital, Manila
- Vicente Sotto Memorial Medical Center, Cebu
- Rizal Memorial Medical Center, Manila

Taiwan

- National Taiwan University Hospital, Taipei
- Kaohsiung Veterans General Hospital, Kaohsiung