

NCIC CTG

# Genitourinary Newsletter

## General Updates

### Welcome back Dr. Wendy Parulekar!

And a big THANK YOU to Dr. Ralph Meyer for taking such good care of the GU disease site!

### NCIC CTG trials in the Genitourinary Disease site are highlighted in article



The newly activated trials PR.11, PR.12, and PR.13 are highlighted in a new article to be published in the August edition of the Canadian journal Current Oncology: **Defining the Optimal Treatment Strategy for Localized Prostate Cancer Patients: A Survey of Ongoing Studies at the National Cancer Institute of Canada Clinical Trials Group** Wendy R. Parulekar *et al.*

### START trial chosen for April 2009 online issue of ASCO News & Forum

Dr. Ralph Meyer's article detailing the PR.11 or "START" trial (Surveillance Therapy Against Radical Treatment) is available at the following URL: <http://www.asconews.org/anf/News/Research+Issues+%26+Resources>

### IND 165 ASCO Presentation

IND165, a randomized phase II study of docetaxel plus/minus the clusterin anti-sense OGX-011, has now mature progression and survival data and has been selected for oral presentation at the ASCO Annual Meeting in Orlando this year. Study results will be presented, in confidence, at the NCIC CTG spring meeting in the IND and GU meetings.

**Congrats to the Trial Team:** Kim Chi, Elizabeth Eisenhauer, Dongsheng Tu, Jean Powers, Linda Hagerman and Christine Tran



### Important Reminders:

\* Get those forms in! Please do not wait for reminders to be sent, or for the final analysis to roll around before sending in those deficient forms and unanswered query letters. The CPI is watching...



\* Participants List Particulars: Please make sure that participant lists are updated regularly. Missing or incorrect information is not only deficient by GCP standards, but can also result in important safety information getting lost in the wide expanse of cyber-land. Only the PI can sign the Participants List/Participants List Change Form and there must be exactly one PCRA and one ECRA listed (although this may be the same person). ECRA's are not permitted to randomize patients, nor will they be given access to the Electronic Data Capture System. For these privileges, the individual must be coded as ACRA.

\* **PLEASE** do not use the CTSU website to obtain protocols or other trial documents. Always use the NCIC CTG trial website and only act upon notices sent by NCIC CTG and not by the lead group or the CTSU bulletin.

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### Who's on top?

This newsletter pays tribute to those hard working centres who have accrued well to the various GU trials. This could be you...get those trials open asap!

**Questions? Comments? Suggestions?**



**Andrea Hiltz**  
GU Study Coordinator  
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# Trial Spotlight

**PR.13 Accrual as of 2009-APR-17**

## PR.13/MRC PR.10—RADICALS

### RADIODTHERAPY AND ANDROGEN DEPRIVATION IN COMBINATION AFTER LOCAL SURGERY

- \* Two very important questions plaguing the prostate cancer field are the timing of radiotherapy post surgery and the duration of hormone treatment. This “large simple study” attempts to answer these two key questions.
- \* Patients may enter the RT randomization within 5 months from their surgery date, or may enter the Hormone Duration randomization after immediate RT, or at the time of PSA rise post-surgery and when RT is indicated.
- \* Eligible patients may have node positive disease and may have received prior hormone therapy provided it was not within 6 months of randomization.

**CANADIAN: 21  
TOTAL: 150**

NCIC CTG Co-Chairs:

**Charles Catton**  
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NCIC CTG PC:

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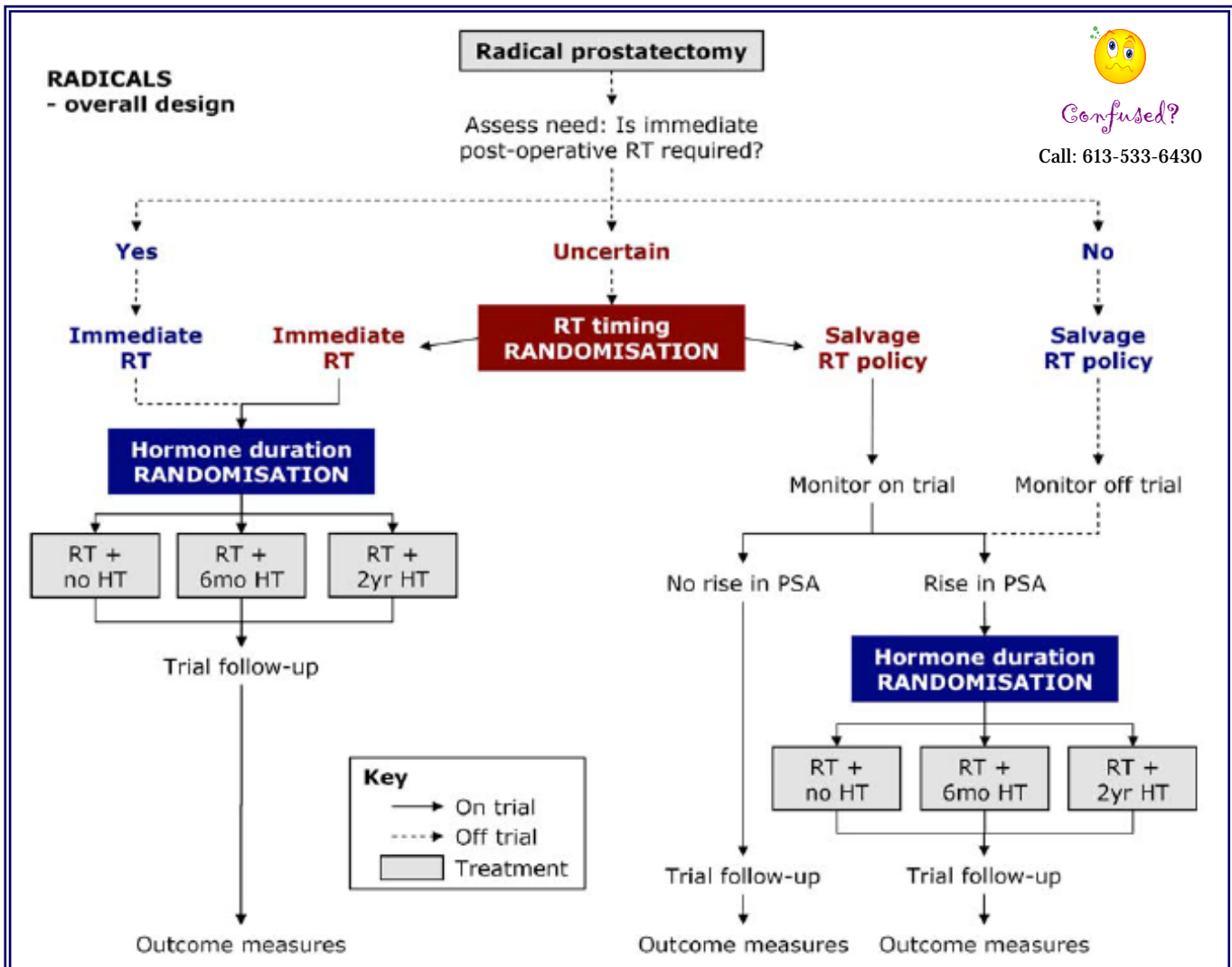
NCIC CTG SC:

**Andrea Hiltz**  
ahiltz@ctg.queensu.ca



**CONGRATULATIONS TO PRINCESS MARGARET HOSPITAL FOR PLACING SECOND IN OVERALL RANDOMIZATIONS: 18!**

Charles Catton, Peter Chung, Robert Bristow, Padraig Warde, Cynthia Menard and Debbie Tsuji



## Open NCIC CTG-led Studies

### PR.11—START

**A PHASE III STUDY OF ACTIVE SURVEILLANCE THERAPY AGAINST RADICAL TREATMENT IN PATIENTS DIAGNOSED WITH FAVOURABLE RISK PROSTATE CANCER**

**Canadian accrual is off to a great START!**

Each centre chosen for the feasibility phase was charged with the task of accruing at least 4 patients in the first year. Over half of Canadian centres have met and surpassed this level! Accrual in the US and the UK remains challenging; however, with the approval of a revised **patient educational video** it is expected that randomizations will start to increase.


  
*Merci*
  
**Centre hospitalier universitaire de Sherbrooke** is leading the way with **16** randomizations!
   
 Abdenour Nabid, Rachel Bujold, Annie Bourbonnais, Sophie Couture, Josee Deharnais, Josee Soucy

**Treatment by patient/physician choice is NOT a protocol violation**

The protocol predicts that approximately 10% of patients randomized to Active Surveillance will choose to undergo treatment in the absence of disease progression. This is part of the study design and will not be considered a protocol violation. Follow-up for patients randomized to Radical Treatment who opt for surveillance will be the same as those who underwent treatment (i.e. do not complete a Form 5AS, but rather a Form 4 followed by Form 5 reports).

### PR.12—DART

**A PHASE III STUDY OF NEOADJUVANT DOCETAXEL AND ANDROGEN SUPPRESSION PLUS RADIATION THERAPY VERSUS ANDROGEN SUPPRESSION ALONE PLUS RADIATION THERAPY FOR HIGH-RISK LOCALIZED ADENOCARCINOMA OF THE PROSTATE**

**EDC forms are no longer a mystery thanks to the Mock CRFs**



Mock CRFs are now available on the PR.12 trial website to help study personnel better understand data collection and reporting prior to logging into the EDC system. Mock CRFs are meant to approximate the actual PR.12 screens in the EDC system and provide users with a “snap shot” of what each e-CRF looks like. These forms are meant to be used as a tool only not as a worksheet. Please do not submit these forms to the NCIC CTG.

**BCCA - Vancouver Cancer Centre** is leading the way with **7** randomizations!
   
 Michael McKenzie, Charmaine Kim-Sing, Scott Tyldesley, Devon Poznanski
   
  
**Newly Activated Centres!**
  
 Lakeridge Health Oshawa
   
 CancerCare Manitoba
   

  
**Welcome!**

**PR.11 Accrual as of 2009-APR-17**

**TOTAL 68**

NCIC CTG Chair:

**Laurence Klotz**  
Lauence.klotz@sunnybrook.ca

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wparulekar@ctg.queensu.ca

NCIC CTG SC:

**Andrea Hiltz**  
ahiltz@ctg.queensu.ca



**PR.11 Patient educational video and public website now available!**



**PR.12 Accrual as of 2009-APR-17**

**TOTAL 24**

NCIC CTG Chairs:

**Michael McKenzie**  
mmckenzi@bccancer.bc.ca

**Kim Chi**  
kchi@bccancer.bc.ca

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wparulekar@ctg.queensu.ca

NCIC CTG SC:

**Andrea Hiltz**  
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## Open CTSU Studies

**PRC.2/CALGB 90202**—A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED PHASE III STUDY OF EARLY VERSUS STANDARD ZOLDRONIC ACID TO PREVENT SKELETAL RELATED EVENTS IN MEN WITH PROSTATE CANCER METASTASIS TO BONE

**PRC.2 Accrual as of 2008-APR-20**

**TOTAL: 368**

**Canadian: 23**

NCIC CTG Chair:

**Fred Saad**  
fred.saad@umontreal.ca

NCIC CTG PC:

**Wendy Parulekar**  
wparulekar@vtg.queensu.ca



The London Health Sciences Centre has randomized 15 patients to this trial!

Keep up the great work!

Joseph Chin, Jonathan Izawa, Wendy Shoff, Joanne Ouellette, Angela Gough, Stephanie Giller, Rebecca Ament

**PRC.3/CALGB 90203**—A RANDOMIZED PHASE III STUDY OF NEO-ADJUVANT DOCETAXEL AND ANDROGEN DEPRIVATION PRIOR TO RADICAL PROSTATECTOMY VERSUS IMMEDIATE RADICAL PROSTATECTOMY IN PATIENTS WITH HIGH RISK, CLINICALLY LOCALIZED PROSTATE CANCER

**PRC.3 Accrual as of 2008-APR-20**

**TOTAL: 97**

**Canadian: 11**

NCIC CTG Chair:

**Martin Gleave**  
martin.gleave@ubc.ca

NCIC CTG PC:

**Wendy Parulekar**  
wparulekar@vtg.queensu.ca

### Important changes in drug supply:

In some provinces, the LHRH agonist therapy for patients randomized to Arm A of this study is not covered by provincial health plans. Sanofi Aventis has recently contracted with the CALGB to provide Eligard® (*leuprolide acetate*) free of charge to Canadian centres. As a result, both the Taxotere® and the Eligard® will be shipped directly to Canadian centres by Sanofi Aventis and will no longer be supplied via the PMB.

Starter supplies of both agents will automatically be sent to centres at the time of local activation, while each subsequent kit must be ordered in time for the patient's next cycle of treatment.

An amended Canadian Intergroup Appendix will be issued shortly that will clearly outline the new processes.



**BCCA - Vancouver General Hospital** is leading the way with **8** randomizations!

Martin Gleave, Kim Chi, S Larry Goldenberg, Maureen Palmer, Tracey Henry, Charlotte Lee

**Newly Activated Centres!**

Lakeridge Health Oshawa, Princess Margaret Hospital, CancerCare Manitoba

## REC.2/ECOG 2805—ASSURE:

**ADJUVANT SORAFENIB OR SUNTINIB FOR UNFAVORABLE RENAL CARCINOMA**

**REC.2 Accrual as of 2008-APR-20**

**TOTAL: 1221**

**Canadian: 85**

NCIC CTG Chairs:

**Michael Jewett**  
m.jewett@utoronto.ca

**Lori Wood**  
lori.wood@cdha.nshealth.ca



This trial is an excellent example of how you must always refer to the NCIC CTG website for all trial documents and not the CTSU site.

A Canadian consent update was issued in October 2008, then the lead group amended the protocol. These were treated separately, because Canadian accrual was to be suspended pending REB approval of the updated consent but US accrual was not.

Then in February 2009, ECOG issued Addendum #5 which involved more consent form changes, but this time accrual was held in the US but not in Canada!

By following the NCIC CTG notices and memos, and ignoring ECOG instructions to centres, problems can be avoided and deficiencies reduced.

The REC.2 trial has a whopping 19 centres open in Canada!

**Princess Margaret Hospital** has randomized a very impressive 17 patients to this trial!

Jennifer Knox, Ian Tannock, Michael Jewett, Neil Fleshner, Srikala Sridhar, Laura Legere, Davina Lau, Iwona Link

NCIC CTG PC:

**Wendy Parulekar**  
wparulekar@vtg.queensu.ca

## Studies Preparing for Interim Analysis

### PR.3—

#### **INTERGROUP (NCIC CTG, CUOG, SWOG, MRC-UK) PHASE III RANDOMIZED TRIAL COMPARING TOTAL ANDROGEN BLOCKADE VERSUS TOTAL ANDROGEN BLOCKADE PLUS PELVIC IRRADIATION IN CLINICAL ADENOCARCINOMA OF THE PROSTATE**

##### **Interim analysis planned**

- \* Thank you for all of your efforts in completing and submitting outstanding forms for patients on the PR.3 trial.
- \* The interim analysis is planned for early summer 2009 with the results being disclosed to the PR.3 DSMC.



##### **Lost to follow-up**

Patients on the PR.3 trial are to receive hormone therapy indefinitely and are to be followed until death. While it is likely that over time patients will stop coming to the cancer clinic for annual visits, it is extremely important to the integrity of the trial that patients, their families or their GPs be contacted once a year to inquire after the patient's status. Preferably enough data is obtained that the yearly Form 5 may be completed in full.

Should repeated efforts to obtain follow-up data be unsuccessful, please submit a letter to the NCIC CTG explaining that despite these attempts, the patient remains lost to follow-up. This letter must be signed by the responsible investigator.



The primary endpoint of both trials is **overall survival** so please ensure the Form 6 is submitted in a timely manner.

### PR.7—

#### **A PHASE III RANDOMIZED TRIAL COMPARING INTERMITTENT VERSUS CONTINUOUS ANDROGEN SUPPRESSION FOR PATIENTS WITH PROSTATE-SPECIFIC-ANTIGEN PROGRESSION IN THE CLINICAL ABSENCE OF DISTANT METASTASES FOLLOWING RADIOTHERAPY FOR PROSTATE CANCER**

- \* PR.7 has completed Amendment #7 as of 2008JUN13. This has resulted in a simplification of the document submission process and most centres are now finding the process more streamlined.
- \* The Interim Analysis is set to occur in early summer 2009. In anticipation of this, we have been cleaning the database and have requested outstanding CRFs to be submitted. Data cleaning and query resolution will be focusing on all data submitted up until the clinical cut off point of 400 events recorded.
- \* A new Study Coordinator is assigned to the trial-Eliot Frymire.

NCIC CTG Chair:

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padraig.warde@rmp.uhn.on.ca

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**Wendy Parulekar**  
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**Andrea Hiltz**  
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#### **A helpful tip...**

When completing CRFs and entering the date of histological confirmation of disease, please always use the date of the surgery or biopsy and not the date that the tissue was reviewed by the pathologist.

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juanita.crook@rmp.uhn.on.ca  
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## Recent trial closures

**BL.8** - NCIC CTG closed this study due to poor accrual on May 09, 2008. The EORTC then proceeded to close the trial worldwide on July 25, 2008.

**BL.11**—NCIC CTG closed this study due to poor accrual on December 03, 2008. All patients were asked to discontinue gefitinib treatment. Data collection is to continue for up to one year following randomization and will then cease.

**PR.8** - This trial has met its accrual goal and as of September 01, 2008, sites will no longer be able to register patients to the early induction phase of this trial. Randomization to the consolidation phase will continue until further notice.

**CONGRATS**: The Tom Baker Cancer Centre, Calgary for accruing 22 patients  
Trial team members: Bryan Donnelley, Bernard Eigl, Dean Ruether, Kelly Maclaughan



**PRP1.B**—This trial was open to all eligible PRP.1 patients. It has now closed to accrual and tissue collection efforts are almost completed. Many thanks to participating centres for their enthusiasm and hard work!

## List of contacts for intergroup trials

**As a general rule:** For CTSU trials (ones that end in a 'C' like REC.2), contact the lead group directly for all trial-related issues and Andrea Hiltz for administrative and regulatory issues.

Trial	Issue	Contact	Phone	Email
<b>PR.8</b> SWOG – 9346 Closed	Eligibility & Treatment	Dr Maha Hussain	734-936-8906	mahahuss@med.umich.edu
	General Issues - Lead Group	SWOG Stat Centre	206-652-2267	
	OTHER - NCIC CTG SC	Andrea Hiltz	613-533-6430	ahiltz@ctg.queensu.ca
<b>PRC.2</b> CALGB – 90202 Open	Eligibility & Treatment	John Taylor	773-702-9171	jtaylor1@uchicago.edu
	General Issues - Lead Group	CALGB	773-702-9171	Ask for 90202 Data Manager
	OTHER - NCIC CTG SC	Andrea Hiltz	613-533-6430	ahiltz@ctg.queensu.ca
<b>PRC.3</b> CALGB – 90203 Open	Eligibility & Treatment	John Taylor	773-702-9171	jtaylor1@uchicago.edu
	General Issues - Lead Group	CALGB	773-702-9171	Ask for 90203 Data Manager
	OTHER - NCIC CTG SC	Andrea Hiltz	613-533-6430	ahiltz@ctg.queensu.ca
<b>REC.1</b> CALGB – 90206 Closed	Treatment and General Issues - Lead Group	John Taylor	773-702-9171	jtaylor1@uchicago.edu
	OTHER - NCIC CTG SC	Andrea Hiltz	613-533-6430	ahiltz@ctg.queensu.ca
<b>REC.2</b> ECOG – 2805 Open	Eligibility & Treatment	Tanya Mustacchio	613-632-3610	mustacchio.tanya@jimmy.harvard.edu
	General Issues - Lead Group	ECOG	617-632-3610	Ask for 2805 Data Manager
	OTHER - NCIC CTG SC	Andrea Hiltz	613-533-6430	ahiltz@ctg.queensu.ca



**Please** use the NCIC CTG trial website to download protocols, forms, memos, amendments, safety reports etc and not the lead group or CTSU website!!!