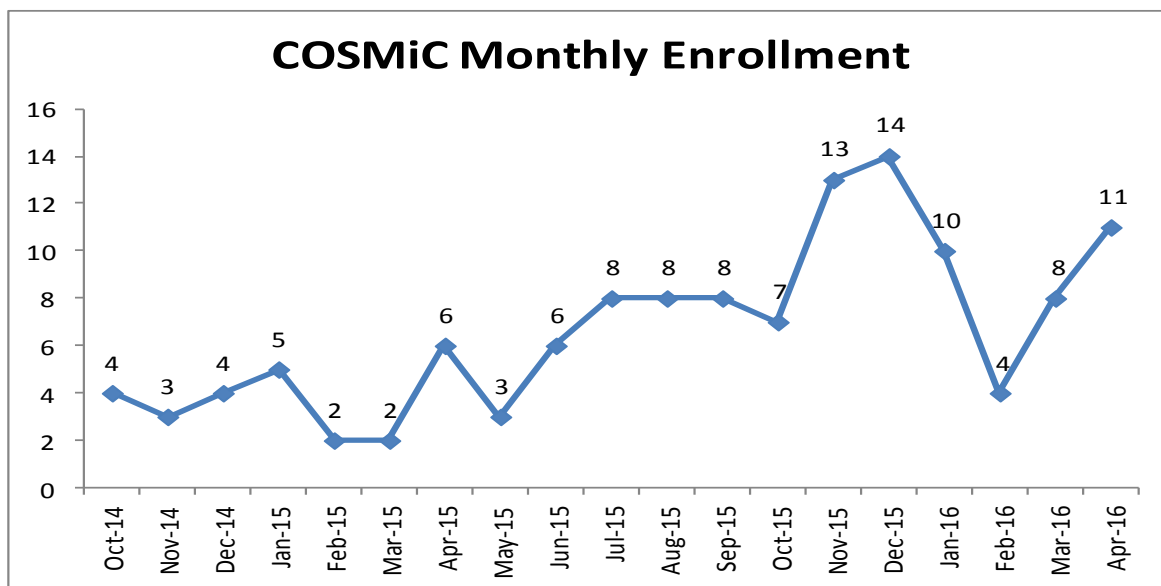




ENROLLMENT UPDATE

April saw 11 subjects enrolled, just shy of our goal of 15 subjects per month. We currently have 128 subjects enrolled and need help from all sites to achieve 250 subjects by the year end.



WELCOME

Welcome to the following new sites to COSMiC;

Dr Joseph Chin—London Health Sciences Centre

Dr Delores Sicheri—Thunder Bay Regional Health Sciences Centre

Dr Philippe Violette— Woodstock, ON



MATERNITY LEAVE

We would like to send our very best wishes to one of our COSMiC Investigators—Dr Michelle Strovski from Maple Ridge, BC on her upcoming maternity leave.

TOP RECRUITING SITES

Investigator	Number of Patients Recruited
Dr Gotto, Calgary, AB	20
Dr Incze, Oakville, ON	12
Dr Zadra, Barrie, ON	9
Dr Drachenberg, Winnipeg, MB	7
Dr Fradet, Quebec, QC	6
Dr Giddens, Brampton, ON	6
Dr Aaron, Greenfield Park, QC	6

COSMIC STUDY SUCCESSES

Urologists, Dr. Geoff Gotto and Dr. Bryan Donnelly, continue to enroll well into the Cosmic study. Their success has been truly a team approach. At the time a Zytiga prescription is written they simultaneously contact the lead study coordinator Cora Carr at the Prostate Cancer Centre (PCC) Calgary, AB. Cora meets with the patient immediately, explains the study and obtains informed consent. Study packages with all necessary documents are prepared ahead of time to ensure a well-organized session is conducted with the patient. Since January 2016, PCC has enrolled nine new patients into the study bringing its total to 20 participants. Due to the overall study site success, the team has raised their goal from 20 to 30 patients and they look forward to seeing what the rest of 2016 will bring.

From: The Team at Dr. Geoff Gotto's site #21.

Dr Incze sees his prostate cancer patients on his clinic days and will evaluate those that would benefit from Zytiga. Once the patient is recommended for Zytiga, the patient is sent to the study coordinator that same visit. Patients at this site appreciate the fact that the site is completing all the paper work for the drug. The patients are very comfortable being in the study and they feel the security of being followed on Zytiga and look forward to receiving their blood work results. We have 12 patients and will be enrolling the 13th patient soon.

From: Rupi Dhaliwal and the study team at Dr Incze's site #01.

MESSAGE FROM DR CASEY

At this year's CUA, CMX will be exhibiting their booth. Please stop by and visit us and let us have some feedback on your COSMIC patients. Preliminary data will be presented at the conference and it's always good to hear from our investigators first hand.

Patients are starting on therapy a little earlier than those when the drug was introduced and this is expected. It hasn't taken long for second line AA therapy to be accepted as the standard of care in many Urology practices. Data from COSMIC should support the utility of this intervention, particularly if we remember what the clinical course of many of these men was prior to abiraterone's introduction.

Those investigators participating need to enter CRPCa patients so we can evaluate its effect in the general Urologic population. I sense that second line agents will soon replace AA's that we've used for years and the monitoring will be easily incorporated into our practice routines. Will more complete androgen blockade allow our CRPCa patients to delay chemo even longer, as we apply it earlier or in less advanced, but metastatic patients?

Help us meet COSMIC's goal of 250 patients by years end. Your feedback is always appreciated anytime through the course of this study.

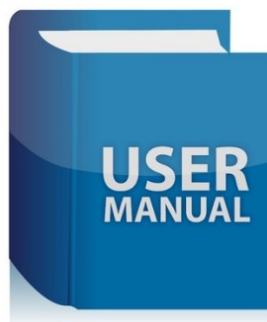
Dr Richard Casey MD, FRCS(C)
CEO & Medical Director
CMX Research Inc.

REPORTING AE's/SAE's in the eDC

- Investigators/ study personnel should report **ALL** AE's and SAE's in this patient population after the patient has consented to enroll into the COSMiC study.
- All AE's must be reported in the EDC within **5 days**
- All SAE's must be reported in the EDC within **24 hours**. The SAE eCRF should be printed and faxed immediately with the SAE Fax Cover Page located in your Site Master File to CMX at **1-905-248-3307**
- In the event that the EDC is down please complete the paper SAE form located in your Site Master File
- **Note that whether it is an AE or SAE, please complete both the AE and SAE forms in the EDC, since in the case it is only an AE you can indicate it is not an SAE in the first question of the SAE form**

EDC USER MANUAL

An EDC User Manual for the COSMiC Study is now available and a copy will be sent to all sites. The manual can also be found in Meraki App on the iPad home screen. It details System Navigation, Managing Subjects, Events and ePROs, eCRFs and Query Resolution.



ADVISORY BOARD MEETING at the CUA



Janssen and CMX will be holding an Advisory Board Meeting at this years CUA on Friday June 24th from 2-5pm at the Westin Bayshore.

CANADIAN UROLOGICAL ASSOCIATION

Both Janssen and CMX will be present at the upcoming Canadian Urological Association 2016 Meeting in Vancouver, June 25-28, 2016. Please stop by our exhibitor booths and introduce yourself!!

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