

# CTNZ Newsletter

June 2013 | Quarterly newsletter | Number 15

## Cancer Trials New Zealand is 10 years old this year!

In 2003 CTNZ became a reality with the awarding of a seeding grant from the Cancer Society Auckland – importantly their continued support over the subsequent 10 years has enabled us to develop and sustain our activity and workforce.

We plan to celebrate our first decade at our **Annual Scientific Meeting (ASM) on Monday 1 July**. This meeting is in Dunedin and will be back-to-back with the New Zealand Society of Oncology Annual Scientific Meeting (2-3 July).



Our Director, Michael Findlay will start off the day with CTNZ's 'trials and tribulations' over the first ten years. This will be followed by a packed programme with the usual interesting updates on our current trials and studies plus presentation and discussion of new study concepts. Following in from a popular session on data management and methods last year we have created a regular slot at the ASM for a topic in this area – we are sure you will find this year's topic very interesting and useful. To view the current programmes please visit [www.ctnz.auckland.ac.nz](http://www.ctnz.auckland.ac.nz)

We are looking forward to hearing from the PIPER team who will be presenting the challenges that have been experienced by all involved with the data collection, this will be a very interesting presentation and will no doubt offer guidance and advice for anyone thinking of doing a similar observational study / audit in the future.

We are fortunate to have **Professor John McCall** as our guest speaker this year. John will not have far to travel as he is based at the Dunedin School of Medicine where he holds the McKenzie Chair in Clinical Sciences. John is going to talk about **"Key Clinical Research Strategies for Colorectal Cancer"** drawing on his current interest in laboratory and clinical research in primary and metastatic colorectal cancer.

Our ASM is on Monday 1 July 10.30am - 4pm, we hope you will be able to join us for our meeting and also to help us celebrate 10 years of CTNZ. Please contact Kasturi ([k.naicker@auckland.ac.nz](mailto:k.naicker@auckland.ac.nz)) to register your interest. See you in Dunedin for some birthday cake!



Hello again from us at CTNZ on our 10<sup>th</sup> birthday. We have achieved a lot during this time and this is primarily due to the wonderful people we have at each of our collaborating sites and at the CTNZ operations centre. Whilst we have excellent investigators I would like to especially thank the very professional group of trial coordinators, research nurses and research managers who help us get every step of the research process completed – both at each cancer centre and at CTNZ. Obviously although none of this would happen without you all, I am sure you would join me in acknowledging the ultimate contribution made by patients, who with much on their mind at the time, have agreed to participate in trials and 'give something back'. For them CTNZ has to do better in its next 10 years - join us in that challenge.

## Upcoming Meetings:

### **CTNZ Annual Scientific Meeting**

1<sup>st</sup> July 2013, Dunedin

### **New Zealand Society for Oncology (NZSO) 2013 Conference**

2-3 July 2013, Dunedin

### **National Rectal Cancer Summit**

9<sup>th</sup> August 2013, Wellington

### **NZACRes**

23<sup>rd</sup> August 2013, Auckland

### **Queenstown Molecular Biology Meeting**

25<sup>th</sup>-30<sup>th</sup> August 2013,  
Queenstown

### **17<sup>th</sup> ECCO – 38<sup>th</sup> ESMO – 32<sup>nd</sup> ESTRO European Cancer Conference**

27<sup>th</sup> September- 1<sup>st</sup> October  
2013, Amsterdam

### **15<sup>th</sup> Australasian Gastro Intestinal Trials Group (AGITG) Scientific Meeting 2013**

8<sup>th</sup>- 10<sup>th</sup> October 2013,  
Melbourne

### **Clinical Oncological Society of Australia (COSA) 40<sup>th</sup> Annual Scientific Meeting**

12<sup>th</sup>-14<sup>th</sup> November 2013,  
Adelaide

For more information see our  
Meetings Calender

Visit our website

[www.ctnz.auckland.ac.nz](http://www.ctnz.auckland.ac.nz)

## **Annual Meeting of The Society for Clinical Trials, Boston**

In May I attended the Annual Meeting of The Society for Clinical Trials, held in Boston. It would be hard to beat the Boston springtime as a conference location, and the conference itself was also very worthwhile. The Society publishes the journal Clinical Trials, and has very diverse membership. The conference reflects this diversity, presenting pre-conference workshops and invited sessions on a broad range of topics across trial design, conduct and analysis.

The plenary "Curtis Meinert Lecture" this year was given by Atul Butte on "Transforming 300 Billion data points of data into Diagnostics, Therapeutics and new insights into disease". Several sessions presented novel designs for improving the efficiency of trials, although in several cases the increased efficiency came at the cost of interpretability of results. There was discussion of the issue of compliance with study protocols (based on evidence from mandatory reporting at ClinicalTrials.gov); and discussion of the conduct of trials in specialised settings such as nursing homes, emergency medicine and the community.

Risk-based monitoring was discussed in several sessions, following the recent release of the FDA Guidance document that stressed the importance of central monitoring with less reliance on on-site monitoring (FDA. Draft Guidance: Guidance for Industry Oversight of Clinical Investigations – A Risk-based Approach to Monitoring). Another session discussed experiences in the implementation of the New Safety Reporting Regulations (based on new rules released in 2010), where the goal was to streamline safety reporting to the FDA. The role of endpoint adjudication was discussed (recommending an audit-based approach rather than full adjudication of all endpoints).

There was also a discussion of the initial experiences of the US Cancer Cooperative groups with implementing the National Clinical Trials data management system (the NCI supported ADOPTION of New Technologies (ADOPT) for remote data capture). The final session was on Data Monitoring Committees of the future, and focussed mainly on the need for training through apprenticeship style experience, a system which we set up in New Zealand many years ago with the HRC Data Monitoring Committee. I am grateful to the University of Otago for supporting my attendance.

– **Associate Professor Katrina Sharples**

## Projects and Current Trials Update

### The PIPER Project

#### Presentations Investigations Pathways Evaluation Rx

We closed last year with 1000 patients on the database. Six months later we have nearly tripled that figure with data collected for 3037 patients, out of the 6540 total required. Although we have done really well in the last 6 months we will have to extend the data collection phase in order to reach our target. Delays have resulted from the extended pilot phase, and difficulty in obtaining all the required data per case across multiple sources, particularly in our centres that cover wide geographical areas, and also in collating data from the private sector. We are currently looking into funding avenues to supplement these extensions.

Data cleaning has begun on the cases collected to date. We will also be extracting our first set of data from the National Minimum Dataset (hospital admissions) within the next month. The summer studentship project to investigate the quality of ethnicity data taken from the medical records, is also in the planning phase and will be conducted over Dec/Jan 2013-14. A more detailed update on the PIPER Project along with a presentation on the challenges of collecting clinical data on this large scale will be given at the CTNZ ASM 2013 meeting and at the 2013 NZSO conference. For any queries/information please contact Melissa [m.murray@auckland.ac.nz](mailto:m.murray@auckland.ac.nz)

### The NETwork! Programme

#### The NET Registry

Entry of cases into the NET Registry has begun and we currently have 150 patients registered on the database. At present this has all been centralised by CTNZ but the aim is to roll out data collection across the regional cancer centres. A new web-based portal for entering data is currently being tested and will be showcased at the CTNZ ASM on the 1<sup>st</sup> July 2013.

#### The NETwork! Genomics study

Ethical approval has recently been given to start prospective collection of tissue samples from around the country. Individual site localities are currently being worked through. Please contact Melissa [m.murray@auckland.ac.nz](mailto:m.murray@auckland.ac.nz) if you are able to assist in providing tissue for this exciting project.

Preliminary testing has been undertaken to optimise the methods for DNA and RNA extraction from tumour tissues and dried blood spots. Twelve pilot tumours are about to be processed to perform whole genome and enriched exome sequencing on the DNA samples and mRNA and whole transcriptome sequencing on the RNA samples. This will be expanded into further patient samples using more focussed genomics approaches, as directed by the data from the pilot studies. We are also optimising protocols for processing of formalin blocked tumours to make use of the large archives of tumour tissue available. Tissue for this project will also be collected retrospectively. Approval for this will be sought through a separate ethics application, which is currently in progress.

## SIRFLOX and FOXFIREGlobal

SIRFLOX has completed recruitment and most patients are now undergoing follow up assessments. Data cleaning is ongoing for those that have progressed in the liver. We are open to recruitment at Auckland for FOXFIREGlobal. The other four sites in New Zealand are still pending approval. Three patients have been recruited globally, from 2 sites in Australia.

For further details about SIRFLOX of FOXFIREGlobal please contact Monica: [m.mccusker@auckland.ac.nz](mailto:m.mccusker@auckland.ac.nz)

## SOLD

International recruitment now stands at 1770 patients recruited to this study, including 94 New Zealand patients. The study recruitment target is 3000 patients. Patient accrual in New Zealand has picked up but mainly in Auckland, we need to increase recruitment country-wide to meet the study targets for New Zealand. Please continue to consider the SOLD study for patients with early breast cancer.

For any queries relating to the SOLD study please contact Sarah: [s.benge@auckland.ac.nz](mailto:s.benge@auckland.ac.nz)

## DARECK

DARECK is an open-label, randomised, global, multicentre Phase II trial designed to estimate the efficacy of 'Genentech Study Drug' when combined with FOLFIRI chemotherapy in patients with KRAS wild-type metastatic colorectal cancer (mCRC) who have progressed on or after first-line oxaliplatin-

Eligible patients are randomized in a 1:1 ratio to one of two treatment arms:- Arm A (experimental arm): FOLFIRI + 'Study Drug' or Arm B (control arm): FOLFIRI + Cetuximab. Genentech/Roche are the sponsors of the study. The study is being coordinated in Auckland by CTNZ in conjunction with the Auckland regional Blood & Cancer Service and the monitoring is carried out by Covance NZ.

There are four New Zealand centres participating in the study: Tauranga (lead site), Auckland, Christchurch and Dunedin. Overseas centres participating in the study are: Australia, Belgium, France, Germany, Italy, Romania, Spain, UK and US. Australia is currently the highest recruiting country partly due to their national standard of care KRAS screening program. Nationally there are 6 patients and globally 57 patients on the study. This is 52.5% is of the total 120 patient target. Recruitment currently closes in October 2013.

For further information about DARECK please contact Penny: [penny.kirkwood@auckland.ac.nz](mailto:penny.kirkwood@auckland.ac.nz)

## Trial Recruitment

(as at 10<sup>th</sup> June 2013)

### SIRFLOX (final)

Dunedin	30
Auckland	28
Christchurch	20
Palmerston North	8
Wellington	2
<b>TOTAL</b>	<b>88</b>

### SOLD

Auckland	74
Christchurch	11
Dunedin	7
Wellington	2
<b>TOTAL</b>	<b>94</b>

For further information about these trials, including trial contacts please visit our website:

[www.ctnz.auckland.ac.nz](http://www.ctnz.auckland.ac.nz)



## MELVAC

Ethics, SCOTT and Maori approval have been received for both the Phase I and Phase II protocols. The first vaccine creation validation run with non-GMP product has been completed successfully. Further non-GMP validation runs are scheduled. The first vaccine creation validation run with GMP product is on track to take place in August 2013. Development of the clinical trial database and case report forms is well advanced. The clinical study, based in Wellington at the Blood & Cancer Centre and run by Dr Catherine Barrow, will open soon after. For further information regarding the trial please contact Penny: [penny.kirkwood@auckland.ac.nz](mailto:penny.kirkwood@auckland.ac.nz)

## CTNZ Staff

### Goodbye Sanjeev!

Our Research Fellow, Sanjeev Deva heads off to the UK with his family. Sanjeev will be a Clinical Research Fellow in Experimental Oncology at the King's College London School of Medicine. Thank you Sanjeev for being a wonderful member of the CTNZ team – we look forward to seeing you back soon.



**Congratulations to Associate Professor David Perez** for being awarded an Officer of New Zealand Order of Merit.

**Congratulations** Jade Scott and Hamish Scott on the arrival of their second son Kian Scott.



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With thanks to  
the Cancer Society of NZ,  
Auckland Division