



UNBLINDED

SEPTEMBER 2010

A WORD FROM OUR PRESIDENT...

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Welcome to the third issue of Unblinded. We hope you have all enjoyed the Conference held at SkyCity Convention Centre in Auckland. It was good to see familiar and new faces at the conference. We hope to see you again next year.

The draft copy of the standardised Clinical Trial Agreement has now been sent out to all our members for your feedback. Once finalised, this template will be beneficial to our industry and will save time for all parties involved giving more time for patient care and recruitment.

The website is on track for the upgrade, we are aiming to launch the new look of the website by December.

As you all know by now, Christchurch was hit with an earthquake on the weekend after the Conference. We are all very fortunate that although there is great damage to roads and buildings, there was no loss of life. It amazes me how people in Christchurch have remained very positive despite their ordeal, some of whom have lost their home and possessions. Like a good martini from a James Bond movie, they are "Shaken, not stirred."

Thank you to everyone who checked in with their peers to see what they can do to help. Our thoughts and prayers are with our friends, families and colleagues in Christchurch. We pray that your city will recover soon.

Although the ground they stand may quake, it will not shake their human spirit.

NZACRES FINANCIAL YEAR AND 2011 AGM

Following recommendations from members at last year's AGM, the committee has contracted the services of an external party to annually review the financial results of NZACRes and issue an Independent Report. In line with this process, NZACRes Financial Year has been set as 1st January to 31st December (as per our Constitution) which will allow time to capture all activity from that year's conference.

It is important to have a complete financial report available for our members at the AGM and, for this reason, the current Executive Committee have agreed that the next AGM should be in February March 2011. We anticipate that this decision will not only serve the purpose of having a completed and reviewed Financial Report, but also be at a time to attract a greater attendance number at the meeting. Confirmation of a date will notified closer to the time.

For our sins, the current Executive Committee will continue for a further 3 months until the next election of committee.

We are all inventors, each sailing out on a voyage of discovery, guided each by a private chart, of which there is no duplicate. The world is all gates, all opportunities"

Ralph Waldo Emerson

Do you have the time and/or passion to contribute to the growth of NZACRes ?
If this is you, or someone you know, we will be calling for nominations for volunteers for next year's committee soon.

STANDARDISED CLINICAL TRIAL RESEARCH AGREEMENT

Goal: To develop a standardised Clinical Trial Research Agreement (sCTRA) for use in contract clinical trials in New Zealand, consistent with international practice.

Purpose: To save time, money and manpower in order to facilitate the approval process.

Outcome: To have a streamlined contract negotiation process in order to reduce clinical trial start-up times and to ensure that New Zealand remains an attractive location to conduct clinical research.

Our thanks go to everyone who submitted Schedule 7 changes / comments that have previously been requested when using the Medicines Australia templates in Australia.

As updated at the New Zealand Association of Clinical Research Annual Conference at the SkyCity Convention Centre in Auckland, the sCTRA Writing Group has drafted an initial New Zealand sCTRA template following receipt of the Schedule 7 feedback. If you were unable to attend the conference, please visit www.nzacres.org.nz to view the presentation.

The sCTRA Writing Group has amended the Medicines Australia template to New Zealand requirements and has reviewed each clause in the template. Schedule 7 feedback was reviewed, however unless there was a clear majority of support for an amendment, the content was retained as per the Medicines Australia template.

The sCTRA Writing Group has aimed to be as objective as possible throughout the review and revision process in order to fairly represent the interests of all the parties involved. The review of the body of the agreement has focused on amending the language to fit the New Zealand context around relevant New Zealand regulatory authorities and so forth. The result is that the first draft largely mirrors the Medicines Australia agreement.

Next Steps

As previously communicated, in order to make the standardised agreement receptive to all within our industry, and prior to finalising the agreement, the sCTRA Working Group would now like your **input on the first draft of the New Zealand sCTRA template. We would appreciate receiving generic feedback and that company specific items are reserved for inclusion in Schedule 7.**

Please visit the home page of www.nzacres.org.nz to:

- Download a PDF of the draft New Zealand sCTRA Agreement – changes tracked
- Download a PDF of the draft New Zealand sCTRA Agreement – clean copy
- Download a copy of the feedback spreadsheet

Timeframe

Please email your feedback to be considered by the sCTRA Working Group by close of business **Friday 8 October 2010** to info@nzacres.org.nz with the subject line “sCTRA Working Group”.

“What is research
but a blind date
with knowledge?”

Will Harvey

STRATEGIC DIRECTION UPDATE

The period for providing feedback on the draft Strategic Plan has closed and the feedback is currently being collated and reviewed by the Strategic Direction Sub-committee. NZACRes hopes to launch the new Strategic Plan before the end of 2010.



2010 NZACRES CONFERENCE

The 7th annual Clinical Research Conference titled “Collaboration – The Key to Success” was held on the 26th – 27th of August at the SkyCity Convention Centre in Auckland. This year we hosted our inaugural Conference Gala dinner and dance function with guest speaker Ray Avery, 2010 New Zealander of the Year. The conference event followed the previous year’s format of interactive workshops on the first day and keynote speakers on the second day, all from a variety of speciality within our industry.

There were 6 workshops available and these covered a range of topics from Clinical Research Nursing – career development pathways; Best Practice for Site Monitoring and Management; Alternative Trial Design; Budgeting and Contract Negotiation for Trial Success; Clinical Trials Overview of Design, Data Management and Analysis Aspects; and Building Personal Resilience. These were interesting and practical sessions where delegates shared their ideas and experiences and learned from the speaker and the group as a whole.

The second day of the conference was chaired by Dr. Stewart Jessamine and Dr Chris Wynne. With our notable MP and Chairman of Health Select Committee, Dr. Paul Hutchison opening topic on Improving New Zealand’s Environment to Support Innovation Through Clinical Trials. Hilda Fa’asalele, General Manager of Pacific Health for ADHB following on with Collaboration between ADHB and Pacific Church Communities – supporting communities to make a change. Jamie Mannion, Founder of GetParticipants.com – presenting Modern Approaches to Effective Participant Recruitment. Director of the Queensland Clinical Trials & Biostatistics Centre, Dr. Sanjoy Paul presenting studies in the Management of Type 2 Diabetes Patients and a Simulation Study to Explore Long-Term Scenario. Associate Professor Tony Merriman, Professor of Biochemistry at University of Otago presenting on Genetics of Gout in NZ. Followed by Michelle Lockhart from University of Auckland discussing The State of Clinical Research in NZ. Professor Rod Jackson presenting a Public-Private partnership generating NZ’s largest cohort study – PREDICT. Manager of Ethics Committees, Rohan Murphy speaking about the Systems of Ethical Review. Dr. Samar Issa, Clinical Director of Middlemore Tissue Bank discussing the Middlemore Tissue Bank and the importance of Genetic testing. Professor Alan Barber, Professor Richard Faull and Professor Mike Dragunow from Centre for Brain Research University of Auckland sharing the Collaborative Success between Scientists, Clinicians and the Community. Dr. Jocelyne Benatar, Cardiovascular Research, Auckland City Hospital sharing an Investigator’s Perspective on Informed Consent. And Mike Sabin, Director of MethCon Group Limited showing the effects of Methamphetamine Addiction for long term users.

The conference ended with our social networking event where we celebrated the successful collaboration in our industry. This conference is a reflection of the dedication and hard work of individuals and the different companies that work together as a collective whole in NZ clinical research.

Thank you to all of our sponsors and delegates who attended the conference. We hope you enjoyed the conference and we will see you again next year!

Thank you once again to our NZACRES Conference Organising Committee for putting together a great programme.

Conference Organising Committee members:

Blair Dickman – Pharmaceutical Solutions

Kathryn Adams – Wellington Regional Hospital

Lynda Mockett – CCRep (Centre for Clinical Research and effective practice)

Mario Pennisi – QCTN (Queensland Clinical Trials Network)

Tim Sato – Auckland District Health Board

Tracy Schuurman - GLCC (Green Lane Coordinating Centre)



The conference chairs setting the scene for a great day



Networking and catching up with colleagues.

“Medical science has proven time and again that when the resources are provided, great progress in the treatment, cure and prevention of diseases can occur.”

Michael J Fox



Dr Paul Hutchison’s opening address.

DEVELOPING OPPORTUNITIES AND COLLABORATIONS

Part of the Executive Committee's objective over the 2009–2010 has been to identify key organisations with whom our members will benefit from augmenting these relationships.

NZACRES SIGNS AFFILIATION AGREEMENT WITH NZBIO

NZACRes and NZBIO have signalled their intentions to work more closely together by the signing of a formal Affiliation Agreement between the two organisations. The agreement provides a platform for collaboration, advocacy and mutual promotion as well as providing members of each organisation a discounted rate for attendance at one another's events.

RMI REBRAND AS MEDICINES NEW ZEALAND

A function was held in Wellington on 14th of September to launch the new name, vision and mission for "Medicines New Zealand", formerly the "Researched Medicines Industry Association of New Zealand". Importantly for NZACRes a key strategic goal for Medicines NZ is "Encouraging and supporting an environment that encourages clinical research and medical innovation in New Zealand". As organisations with some mutual interests there are opportunities for NZACRes and MNZ to work together for mutual benefit, the NZACRes Executive look forward to a further developing relationship starting with working together towards this mutual goal.

The great question that has never been answered, and which I have not yet been able to answer, despite my thirty years of research into the feminine soul is "What does a woman want?"

Sigmund Freud

ANOTHER FUNDING SOURCE/OPPORTUNITY

Here is some information about how researchers can get funding for certain research projects, specifically those with commercialisation potential: <http://www.frst.govt.nz/files/TechNZ%20Fact%20Sheet%20Voucher%20August%202010.pdf>



Daffodil Day coincided with our conference and what a colourful touch they added.

NZACRES WEBSITE

It has begun...The NZACRes website has a new layout! Your Executive Committee along with Fuel Design are working hard to ensure our new website is not just aesthetically pleasing, but functional and containing useful information. Our aim for the new-look website is to help market our industry and serve as an information hub for our local and international peers.

The new and improved NZACRes website will be launched in **December 2010** and if you would like to contribute and be a part of the website revamp, have any suggestions in terms of contents, features and functionality, please email info@nzacres.org.nz

After all, this is YOUR WEBSITE and we want to know what would benefit and work best for you as an NZACRes member!

ALL CONTRIBUTIONS THANKFULLY RECEIVED!

We encourage **you** to contribute to the Unblinded Newsletter!

News items, articles, announcements, interesting URLs or ideas you want to discuss or share with your colleagues can be sent info@nzacres.org.nz.

