Breast Oncology Clinical Trials

2012 RESEARCH REPORT

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GREAT HEALTH AND WELLBEING

BREAST ONCOLOGY CLINICAL TRIALS

PRINCIPLE INVESTIGATOR: DR JACQUI CHIRGWIN

Breast oncology clinical trials, led by Dr Jacquie Chirgwin, have undertaken research at Eastern Health (Box Hill and Maroondah campuses) since 1995. Over 17 years, 570 patients have been recruited to 54 clinical trials and eight local studies have been initiated. Trials are funded purely from the study sponsors (via per patient payments) and a small annual grant from the Cancer Council of Victoria.

Clinical trial activity has predominantly been on phase II to IV clinical trials, but in recent years also includes a number of locally developed studies and retrospective reviews.

From July 2011 to June 2012, 75 new patients have been recruited to clinical trials and an additional 369 continue on treatment or follow up.

THE BREAST ONCOLOGY CLINICAL TRIALS TEAM INCLUDES:

Medical Oncologists

- Dr Jacquie Chirgwin (Principal investigator)
- Drs Sue Chua, Laura Pellegrini, Serene Foo, Geraldine Goss (Co-investigators)

Breast Surgeons

- Mr Michael Law and Mr Rick Masters (Principal investigators)
- Mr David Stoney, Mr Sunny Jassal, Miss Suzanne Moore, Associate Professor Jenepher Martin and Mr Michael Cheng (Co-Investigators)

Registrars

- Drs Siew Wei Wong, Mei Lung, James Whittle
- Drs Danielle Ferraro and Wee-Kheng Soo continue as external co-investigators completing a study.

Nursing and Allied Health

- Anna Boltong, PhD Candidate (Dietician)
- Eva Yuen, PhD scholar, Deakin University
- Associate Professor Patricia Livingston, Deakin University

Clinical Trials Coordination

- Julie Dryden and Amy Tang (Research nurses)
- Angeline Thompson (Administrative assistant)

Breast oncology clinical trials' affiliations include the Breast Services at Maroondah and Box Hill hospitals, Deakin University, Monash University, ANZ Breast Cancer Trials Group and several international breast cancer clinical trials groups.

NOTABLE 2011-12 FUNDING

Attendance at the Australia & New Zealand Breast Cancer Trials Group (ANZBCTG) Annual Scientific Meeting
Avon Travel Grant Tang A, Hobart, July 2012.
Breast cancer research, Cancer Council Victoria, CTMS Grant for Maroondah Hospital and Box Hill Hospital. $33,000.

INVESTIGATIONS IN PROGRESS

Investigations successfully progressing across the year have included:

Open for Recruitment during 2011-12:

Cooperative group studies

ANZ 02P2/IBIS II (DCIS): An international multicentre study of tamoxifen vs anastrozole in postmenopausal women with hormone sensitive ductal carcinoma in situ
Study Chairs: Cuzick J, Howell A, Forbes J. Local investigators: **Law M, Masters R.** Comparing the efficacy of tamoxifen versus anastrozole as treatment for women with early breast cancer. Total Eastern Health recruitment: 10. Recruitment closed February 15, 2012. The trial remains in follow-up.

ANZ 02P2/IBIS II (Prevention): An international multicentre study of anastrozole vs placebo in postmenopausal women at increased risk of breast cancer
Study Chairs: Cuzick J, Howell A, Forbes J. Local investigators: **Law M, Masters R.** Investigating the role of anastrazole in breast cancer prevention in high risk individuals and those treated for DCIS. Total Eastern Health recruitment: 13. Recruitment closed February 15, 2012. The trial remains in follow-up.

ANZ 0802 CIRG/TRIO 012 Docetaxel +/- Imclone CP12-0606 (angiogenesis inhibitor) in metastatic breast cancer
Study Chair: Gelmon K, Martin M, Mackey J, McCarthy N. Local investigators: **Chirgwin J.** Determining if Imclone CP12-0606 (ramicirumab) with standard taxotere chemotherapy will improve progression free and overall survival. Total Eastern Health recruitment: 3. Recruitment closed November 2011. The trial remains in follow-up.

ANZ1001 SORBET A single arm phase II study of the efficacy of tamoxifen in triple negative but oestrogen receptor beta positive metastatic breast cancer
Study Chairs: Phillips K, Keily B. Local investigator: **Chirgwin J.** Determining if tamoxifen has efficacy in this setting. Total Eastern Health recruitment: 0.

ANZ 0501 LATER: Late adjuvant letrozole
Study Chairs: Forbes J, Green M. Local investigator: **Chirgwin J.** Determining if letrozole can reduce the incidence of a breast cancer event in women who are off treatment and whose breast cancer was more than six years ago. Total Eastern Health recruitment: 13. Recruitment closed March 2012. The trial remains in follow-up.

Goserelin: Quality of life study in young women choosing adjuvant ovarian suppression in preference to chemotherapy
Study Chair: Saunders C. Local investigator: **Chirgwin J.** Investigating the decision-making and satisfaction of young patients choosing ovarian suppression (zoladex) or chemotherapy for early breast cancer. Total Eastern Health recruitment: 2.

IBCSG 22-00 Maintenance chemotherapy in Hormone Non-responsive Breast Cancer
International study Chair: Colleoni M. Local investigator: **Chirgwin J.** Determining improvement in disease-free and overall survival for patients treated with 12 months low-dose chemotherapy versus placebo following completion of standard adjuvant chemotherapy. Total Eastern Health recruitment: 28

IBCSG 35-07 SOLE: Extended adjuvant letrozole
International study chairs: Colleoni M, Aebi S, **Chirgwin J**, Karlsson P. Local investigator: **Chirgwin J.** Determining whether five years continuous or intermittent extended adjuvant letrozole is more effective in improving survival in hormone receptor positive post menopausal breast cancer. Eastern Health recruitment: 47. Recruitment closed in July 2012. The trial is in follow-up.

IBCSG 35-07/BIG 1-07 SOLE Sub-study: SOLE-EST
International study chairs: **Chirgwin J**, Jerusalem G. This sub-study investigates oestrogen levels during continuous and intermittent letrozole. Total Eastern Health recruitment: 5. Recruitment closed in July 2012. The trial is in follow-up.

Pharmaceutical sponsored studies

D-CARE Study of adjuvant denosumab
Study chair: Braun A. Study Sponsor: Amgen. Local investigator: **Chirgwin J.** Determining if denosumab improves disease-free and overall survival when added to standard adjuvant treatment for high risk early breast cancer. Total Eastern Health recruitment: 22.

LUX-Breast 1 BI 1200.75 Randomised phase III trial of BIBW 2992 (afatanib) versus trastuzumab (both with navelbine) in metastatic HER-2 positive breast cancer failing one prior trastuzumab treatment
Study chair: Uttenreuther-Fischer M. Study sponsor: Boehringer-Ingelheim. Local investigator: **Chirgwin J.** Investigating the efficacy of afatanib in patients likely refractory to trastuzumab treatment. Total Eastern Health recruitment: 1.

MA-31 EGF 108919 Complete study: trastuzumab vs lapatanib as first line treatment of HER2 positive metastatic breast cancer
Study chair: Gelmon K. Study sponsor: GSK. Local investigator: **Chirgwin J.** Determining anti-HER2 treatment efficacy when given in conjunction with taxane chemotherapy. Total Eastern Health recruitment: 5. Recruitment closed October 2011. The trial remains in follow-up.

SHERSig study: study of molecular biomarkers during treatment of metastatic HER2 positive breast cancer
Study chair: Chan A. Study sponsor: Roche. Local investigator: **Chirgwin J.** Investigating molecular markers of response and resistance to anti-HER2 treatments for advanced breast cancer. Recruitment closed December 31, 2011. The trial was completed and closed in April 2012. Preliminary results were presented in December 2011 at the San Antonio Breast Cancer Symposium. In this study to

date, serial biopsies in patients with HER2-positive metastatic breast cancer have been shown to be safe and feasible. Total Eastern Health recruitment: 1.

Local studies

Influences on taste and food pleasure in people receiving chemotherapy and implications for diet, social dining and nutritional status

Investigators: **Boltong A**, **Chirgwin J**, Francis P, Aranda S, Keast R. This longitudinal study is measuring taste function and food pleasure in women receiving chemotherapy for breast cancer before, during and after treatment. This research will support the development of a taxonomy of reduced food enjoyment and a taste assessment framework for use in the clinical oncology setting. Total Eastern Health recruitment: 27.

Closed for recruitment/remaining progress or follow up

Breast cancer studies require long-term follow up, often more than 10 years. While many trials over the 17 years of Eastern Health breast oncology participation have reported results and or principally concluded, many trials remain in active follow-up.

ALTTO: Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation study: A randomised, multicentre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer

Study chairs: Piccart M, Perez E. Local investigator: **Chirgwin J.** Assessing the best adjuvant anti-HER2 treatment – trastuzumab for one year, lapatanib for one year, combined treatment or a sequence of treatment. A scheduled interim analysis, a comparison of disease free survival on the single agent lapatinib versus the trastuzumab arm suggested that lapatinib alone is unlikely to be as effective as the standard treatment of trastuzumab alone. For patients on the lapatinib alone arm, switching to treatment with trastuzumab has been offered to patients. No Eastern Health patients are on this arm. The study continues in follow-up. Total Eastern Health recruitment: 3.

ATLAS: Adjuvant Tamoxifen Longer versus Shorter

Study chair: Davies C. Local investigator: **Chirgwin J.** Determining whether longer adjuvant tamoxifen improves survival in early breast cancer. The study is not yet published; preliminary report presented at ESTRO 2010 indicates a small significant benefit for longer tamoxifen duration. The study continues in long term follow-up until 2015. Eastern Health recruitment: 33.

AVADO: A randomised, double-blind, placebo-controlled, multicentre study to evaluate the efficacy and safety of bevacizumab in combination with docetaxel compared with docetaxel plus placebo, as first line treatment for patients with HER2 negative metastatic and locally recurrent breast cancer

Study sponsor: Roche. Local investigator: **Chirgwin J**. Determining progression free and overall survival benefit of two different dose schedules of bevacizumab (Avastin) in combination with taxotere in advanced breast cancer. The combination of bevacizumab with docetaxel did not significantly impact on the safety profile of docetaxel. Bevacizumab 15 mg/kg every three weeks showed a small significant increase in progression free survival when combined with docetaxel as first-line therapy for metastatic breast cancer compared with docetaxel plus placebo. Although the study has been completed, it remains open at Box Hill Hospital until the last patient discontinues treatment. Total Eastern Health recruitment: 3.

AZURE: Does adjuvant zoledronic acid reduce recurrence in patients with high-risk localised breast cancer?

Study chair: Coleman R. Local investigator: **Chirgwin J.** This study was published in NEJM and did not show an improvement in disease-free survival or overall survival in women with stage II/III breast cancer who received adjuvant zolendronic acid. Interestingly, in a pre-specified subgroup analysis of women who were more than five years postmenopausal, there was improved disease free survival and overall survival. Total Eastern Health recruitment: 10.

BATMAN: Bisphosphanate and Anastrozole Trial - Bone Maintenance Algorithm Assessment

Study chair: Bell R. Local investigator: **Chirgwin J**. Investigating, through the use of alendronate, the maintenance of skeletal health in post-menopausal women with resected stage I-IIIa hormone receptor positive breast cancer who are receiving anastrozole. This study continues in follow up. The interim analysis for BATMAN is currently in progress and a manuscript outlining these findings is in development. A copy will be forwarded to all participating sites when this is finalised. Total Eastern Health recruitment: 11.

BIG 1-98: A phase III study to evaluate letrozole as adjuvant endocrine therapy for postmenopausal women with receptor (ER and/or PgR) positive tumours and "BIG 1-98 Long term follow up study"

Study chair: Thurliman B. Local investigator: **Chirgwin J.** Investigating disease-free and overall survival outcomes with adjuvant tamoxifen, letrozole or a sequence of the two. The study has been extensively published and has demonstrated a small overall survival benefit for treatment with letrozole compared to tamoxifen; the sequence of letrozole followed by tamoxifen is also superior to tamoxifen alone or the reverse treatment for disease-free survival. The study continues in long-term follow-up. Total Eastern Health recruitment: 47.

BCIRG 005: Phase III randomised trial comparing docetaxel in combination with doxorubicin and cyclophosphamide (TAC) versus doxorubicin and cyclophospamide followed by docetaxel (AC>T) as adjuvant treatment of operable breast cancer Her2NEU negative patients with positive axillary lymph nodes

Study chair: Slamon D. Local investigator: **Chirgwin J.** Investigating the relative efficacy of combination or sequential taxane based adjuvant chemotherapy for early breast cancer. This study has been published and revealed that both sequential (AC>T) and combination (TAC) regimens incorporating the three drugs were equally effective but had different toxicity profiles. Total Eastern Health recruitment: 12.

BCIRG 006: Phase III randomised trial comparing doxorubicin and cyclophosphamide followed by docetaxal (AC>T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC>TH) and with docetaxel, platinum salt and trastuzumab (TCH) in the treatment of node positive and high risk node negative adjuvant patients with operable breast cancer containing the HER2NEU alteration

Study chair: Slamon D. Local investigator: **Chirgwin J**. Evaluating the benefit of trastuzumab as adjuvant treatment for early breast cancer with and without anthracyclines. This study was published and concluded that one year of adjuvant trastuzumab significantly improved disease-free survival and overall survival in women with HER-2 positive breast cancer when combined with chemotherapy. The risk-benefit ratio favoured the non-anthracycline TCH regimen over AC-TH due to fewer acuter toxic effects and lower risk of leukemia and cardiotoxicity although both had similar efficacy. Total Eastern Health recruitment: 11.

CIRG TORI 010: A randomised phase II trial of double-blind, placebo controlled AMG 706 in combination with paclitaxel, or open-label bevacizumab in combination with paclitaxel, as first line therapy in women with HER2-negative locally recurrent or metastatic breast cancer.

Study chair: Slamon D, Forbes J. Local investigator: **Chirgwin J**. Determining if the addition of AMG 706, an angiogenesis inhibitor, to standard taxane chemotherapy for metastatic breast cancer will improve the response rate, progression-free and overall survival. This study did not demonstrate any additional benefit with AMG 706. This compound is not being further pursued in breast cancer management. Total Eastern Health recruitment: 1.

Development and validation of a measure of health literacy for caregivers of people with cancer

Investigators: Yuen E, **Chirgwin J**, Osborne R, **Livingston P,** Dodson S, and Batterham R. This project set out to establish elements of health literacy which are relevant to caregivers in order to develop and subsequently validate a new measure of health literacy for caregivers. Results from the study will ultimately facilitate the development of effective interventions to improve caregiver health and wellbeing.

FACE: Phase III study of letrozole versus anastrozole in post menopausal women with receptor positive/node positive

Study sponsor: Novartis. Local investigators: **Chirgwin J**. Comparing efficacy of letrozole and anastrazole as adjuvant treatment for early breast cancer. Efficacy analysis has not yet been undertaken; follow up is continuing. Total Eastern Health recruitment: 11.

Five-year survival outcome study

Investigators: **Chirgwin J, Pellegrini L, Livingston P.** Evaluating disease-free and overall survival outcome according to patient, tumour and treatment characteristics at five years for patients treated for early breast cancer at Eastern Health between 2002 and 2005.

HERA: A randomised three-arm multicentre comparison of one year and two years of Herceptin®, versus no Herceptin® in women with HER2-positive primary breast cancer who have completed adjuvant chemotherapy

Study chair: Piccart M. Local investigator: **Chirgwin J**. Determining the survival benefit of Herceptin when added to standard adjuvant chemotherapy for HER2 positive early breast cancer. The study has been published and is one of the great success stories of breast cancer treatment. It demonstrates a very significant improvement in disease-free and overall survival with Herceptin. Follow-up continues. Total Eastern Health recruitment: 7.

IBCSG 16-98 / BIG 2-97: International exemestane study: randomised double-blind trial in postmenopausal women with primary breast cancer who have received adjuvant tamoxifen for two to three years comparing subsequent adjuvant exemestane treatment with further tamoxifen; also bone sub-study

Study chair: Coombes C. Local investigator: **Chirgwin J**. Determining if the switch from tamoxifen to exemestane (an aromatase inhibitor) following two to three years of adjuvant tamoxifen will result in a disease-free or overall survival benefit. The study has been published and demonstrates a disease-free survival benefit for patients switching to exemestane and an overall survival benefit for patients with node positive disease. The trial remains in follow-up. Total Eastern Health recruitment: 21.

IBCSG 24: SOFT: Suppression of Ovarian Function Trial: A phase III trial evaluating the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine responsive breast cancer.

Study chair: Francis P, Fleming G. Local investigator: **Chirgwin J**. Determining the disease-free and overall survival benefit, if any, for the addition of ovarian suppression to tamoxifen for patients who remain premenopausal or those who regain ovarian function following adjuvant chemotherapy. This study continues in follow up; no results will be available until 2013. Total Eastern Health recruitment: 12.

IBCSG 25: TEXT: Tamoxifen and Exemestane Trial: A phase III trial evaluating the role of exemestane plus GnRH analogue as adjuvant therapy for premenopausal women with endocrine responsive breast cancer; also bone sub-study

Study chair: Pagani O, Walley B. Local investigator: **Chirgwin J**. Determining if there is a disease-free and overall survival advantage for premenopausal women treated with exemestane in conjunction with ovarian suppression over tamoxifen and ovarian suppression. This study continues in follow up and results will not be available until 2013. Total Eastern Health recruitment: 48.

IMPACT: A prospective observational study of neutropenia and anaemia management in subjects with solid tumours receiving myelotoxic chemotherapy

Study sponsor: AMGEN. Local investigator: **Chirgwin J**. Describing the incidence of neutropenia and anaemia and its management in subjects receiving myelotoxic chemotherapy including the

use of granulocyte stimulating factor medications. This study continues in follow-up. Total Eastern Health recruitment: 33.

LATTE Long-term Anastrozole vs. Tamoxifen Treatment Effects

Chief investigator: Cuzick J, Snow J. Local investigator: **Chirgwin J.** Continuing the collection of long term follow-up data for those patients randomised to the mono-therapy arms of the completed ATAC trial. Total Eastern Health recruitment: 8.

Survival outcome in metastatic breast cancer

Investigators: **Chirgwin J**, **Livingston P**, Ferraro D, Soo WK, Craike M, Sharma S. Determining median survival according to patient, tumour and treatment characteristics of patients treated for metastatic breast cancer at Eastern Health between 2003 and 2010.

TEACH: A phase III randomised double blind, multicentre, placebo controlled study of adjuvant lapatinib in women with early-stage ErbB2 overexpressing breast cancer

Study chair: Goss P. Study sponsor: GSK. Local investigator: **Chirgwin J**. Determining whether delayed adjuvant lapatanib will provide improved disease-free and overall survival in HER2 positive early breast cancer not previously treated with an anti-HER2 agent. This study was presented at SABC meeting 2011. It is the first study assessing anti-HER-2 therapy in an early and late adjuvant setting. There was a 17% risk reduction in disease recurrence but it was not significant. It was only significant in the patients with centrally confirmed HER-2 positive disease. A 35% reduction in symptomatic CNS disease was seen in the lapatinib arm. Total Eastern Health recruitment: 10.

INVESTIGATIONS COMPLETE

Investigations successfully completed during the course of the year have included:

Dose intensity of chemotherapy at Eastern Health in 2008

Investigators: **Chirgwin J, Bae S, Yeung Y, Ng S.** Determining the dose intensity of chemotherapy regimens and factors that result in reduced dose intensity. Dose intensity was satisfactory in over 90% of adjuvant patients but was less in neoadjuvant and metastatic patients. Factors contributing to reduced dose intensity included patient/hospital convenience and availability of growth factor support (especially in neoadjuvant setting). A paper reporting the results of the study has been accepted for publication by the *Asia Pacific Journal of Clinical Oncology*. This study achieved a Best Poster award at ASCO 2010. Total Eastern Health recruitment: 131.

NeoGEM: A phase II trial evaluating the efficacy and safety of epirubicin and cyclophosphamide (EC) followed by docetaxel with gemcitabine (DG) (+ trastuzumab if HER2-positive) as neoadjuvant chemotherapy for women with large operable or locally advanced breast carcinoma.

Study chair: McCarthy N. Local investigator: **Chirgwin J**. Determining the complete pathological response rate to neoadjuvant chemotherapy regimen with EC and DG, and to relate this to molecular markers of response. The final results manuscript is currently being drafted. Once this has been accepted to journals the study will be closed out at all sites. Eastern Health recruitment: 9.

Patterns of recurrence study

Study chair: Hamilton A. Local investigator: **Chirgwin J**. Documenting the clinico-pathological characteristics of patients with a first diagnosis of relapsed or de novo metastatic breast cancer in Australia and New Zealand. Data currently being analysed. Total Eastern Health recruitment: 26.

PREVIOUSLY REPORTED STUDIES

Twenty five closed studies have not been included as they have been previously reported in this and other publications.

HIGHER DEGREE INVESTIGATORS IN TRAINING

Boltong A, PhD (year 3), Taste changes during chemotherapy, Melbourne University, F/T (Supervisor Professor Sanchia Aranda, Peter MacCallum)

IN CONCLUSION

Eastern Health breast oncology research continues to represent a successful collaboration of a number of breast cancer clinicians, well supported by a small and dedicated clinical trial coordination team. The unit has continued to be one of the highest recruiters to breast cancer clinical trials in Australia. Breast cancer clinical trials are focusing on smaller patient populations - so called 'niche' trials meaning that patient numbers and available trials are reducing, thus it is important for the unit to develop particular expertise in specific types of trials.

The unit is developing neo-adjuvant trials at Eastern Health and planning to collaborate on such a trial with the Italian Michelangelo Group. The team will continue to develop locally initiated research and involvement with cooperative group trials.

For further information on breast oncology or to discover research opportunities available, please contact the department on: 03 9871 3585 or by e-mail: chirgwin@tpg.com.au

PUBLICATIONS

Journals

Published

Rayson D, Suter TM, Jackisch C, van der Vegt S, Lluch A, van den Bosch J, Vivanco GL, van Gent AM, Wildiers H, Torres A, Provencher L, Temizkan A, **Chirgwin J**, Ferrandina C, Srinivasan S, Zhang L, Richel DJ. Cardiac safety of adjuvant pegylated liposomal doxorubicin with concurrent trastuzumab: A randomised phase II trial. *Annals of Oncology*. 2011; doi: 10.1093/annonc/mdr519.

Yuen EYN, **Livingston PM**, Batterham R, **Chirgwin J**, Dodson S, Osborne R. Development of a framework for measuring health literacy among caregivers of people with cancer: Insights from concept mapping. *Asia–Pac J Clin Oncol* 2011; 7(Suppl. 4): 150 (abstr. 313).

Chirgwin J, Chua SL. Management of breast cancer with (nab)-paclitaxel nanoparticle albumin-bound combination

regimens: A clinical review. *Breast*. 2011 Oct; 20(5): 394-406.

Coleman RE, Marshall H, Cameron D, Dodwell D, Burkinshaw R, Keane M, Gil M, Houston SJ, Grieve RJ, Barrett-Lee PJ, Ritchie D, Pugh J, Gaunt C, Rea U, Peterson J, Davies C, Hiley V, Gregory W, Bell R; AZURE Investigators. Contributor: **Chirgwin J**. Breast cancer adjuvant therapy with zoledronic acid. *N Engl J Med*. 2011 Oct 13; 365(15): 1396-405. Epub 2011 Sep 25.

Slamon D, Eiermann W, Robert N, Pienkowski T, Martin M, Press M, Mackey J, Glaspy J, Chan A, Pawlicki M, Pinter T, Valero V, Liu MC, Sauter G, von Minckwitz G, Visco F, Bee V, Buyse M, Bendahmane B, Tabah-Fisch I, Lindsay MA, Riva A, Crown J; Contributor: **Chirgwin J**. Breast Cancer International Research Group. Adjuvant trastuzumab in HER2-positive breast cancer. *N Engl J Med*. 2011 Oct 6; 365(14): 1273-83.

Eiermann W, Pienkowski T, Crown J, Sadeghi S, Martin M, Chan A, Saleh M, Sehdev S, Provencher L, Semiglazov V, Press M, Sauter G, Lindsay MA, Riva A, Buyse M, Drevot P, Taupin H, Mackey JR. Contributor: **Chirgwin J**. Phase III study of doxorubicin/cyclophosphamide with concomitant versus sequential docetaxel as adjuvant treatment in patients with human epidermal growth factor receptor 2-normal, node-positive breast cancer: BCIRG-005 trial. *J Clin Oncol*. 2011 Oct 10; 29(29): 3877-84. Epub 2011 Sep 12.

Regan MM, Neven P, Giobbie-Hurder A, Goldhirsch A, Ejlertsen B, Mauriac L, Forbes JF, Smith I, Láng I, Wardley A, Rabaglio M, Price KN, Gelber RD, Coates AS, Thürlimann B; BIG 1-98 Collaborative Group; International Breast Cancer Study Group (IBCSG) Contributor: **Chirgwin J**. Assessment of letrozole and tamoxifen alone and in sequence for postmenopausal women with steroid hormone receptor-positive breast cancer: the BIG 1-98 randomised clinical trial at 8.1 years median follow-up. *Lancet Oncol*. 2011 Nov; 12(12): 1101-8. Epub 2011 Oct 20.

Chirgwin J, Sun Z, Smith I, Price KN, Thürlimann B, Ejlertsen B, Bonnefoi H, Regan MM, Goldhirsch A, Coates AS for the BIG 1-98 Collaborative and International Breast Cancer Study Groups. The advantage of letrozole over tamoxifen in the BIG 1-98 trial is consistent in younger postmenopausal women and in those with chemotherapy-induced menopause. *Breast Cancer Res Treat*. 2012; 131:295-306.

Chirgwin J. Do the results of BIG 1-98 assist with patient management decisions? *Transl Cancer Res* 2012;1(2):113-116. DOI: 10.3978/j.issn.2218-676X.2012.03.03

Fallowfield LJ, Kilburn LS, Langridge C, Snowdon CF, Bliss JM, Coombes RC; IES Trial Steering Committee. Long-term assessment of quality of life in the Intergroup Exemestane Study: five years post-randomisation. *Br J Cancer*. 2012 Mar 13;106(6):1062-7.

Regan MM, Leyland-Jones B, Bouzyk M, Pagani O, Tang W, Kammler R, Dell'orto P, Biasi MO, Thürlimann B, Lyng MB, Ditzel HJ, Neven P, Debled M, Maibach R, Price KN, Gelber RD, Coates AS, Goldhirsch A, Rae JM, Viale G; Breast International Group (BIG) 1-98 Collaborative Group. CYP2D6 genotype and tamoxifen response in postmenopausal women with endocrine-responsive breast cancer: the breast international group 1-98 trial. *J Natl Cancer Inst*. 2012 Mar 21; 104(6): 441-51. Epub 2012 Mar 6.

Ribi K, Aldridge J, Phillips KA, Thompson A, Harvey V, Thürlimann B, Cardoso F, Pagani O, Coates AS, Goldhirsch A, Price KN, Gelber RD, Bernhard J; BIG 1-98 Collaborative Group; International Breast Cancer Study Group. Subjective cognitive complaints one year after ceasing adjuvant endocrine treatment for early-stage breast cancer. *Br J Cancer*. 2012 May 8;106(10):1618-25. doi: 10.1038/bjc.2012.156. Epub 2012 Apr 24.

In press

Chirgwin J, Bae S, Yeung Y, Ng S. Dose intensity of chemotherapy at Eastern Health in 2008. *Asia Pacific Journal of Clinical Oncology 2012* (in press).

Abstracts

Goss P, Smith I, O'Shaugnessy J, Ejlertsen B, Kaufmann M, Boyle F, Buzdar A, Fumoleau P, Gradishar W, Martin M, Moy B, Piccart-Gebhart M, Pritchard K, Lindquist D, Aktan G, Rappold E, Williams L, Finkelstein D. Massachusetts Gen Hosp, Boston, MA, United States; Royal Marsden Hosp, London, United Kingdom; Baylor Sammons Cancer Ctr, Dallas, TX, United States; Rigshospitalet, Copenhagen, Denmark; JW Goethe-Universität, Frankfurt, Germany; Royal North Shore Hosp, Sydney, Australia; UT MD Anderson Cancer Ctr, Houston, TX, United States; Centre GF Leclerc, Dijon, France; Northwestern Univ, Chicago, IL, United States; Hosp Universitario San Carlos, Madrid, Spain; Jules Bordet Inst, Brussels, Belgium; Sunnybrook Regional Cancer Ctr, Toronto, ON; Arizona Oncology, Sedona, AZ, United States; GlaxoSmithKline, Collegeville, PA, United States; GlaxoSmithKline, Uxbridge, United Kingdom. [S4-7] Results of a randomised, double-blind, multicentre, placebo-controlled study of adjuvant lapatinib in women with early-stage ErbB2-overexpressing breast cancer. San Antonio Breast Cancer Symposium, United States, December 2011.

CONFERENCES INCLUDING PROCEEDINGS, PAPERS, POSTERS

International

Chan A, Chan S, Price D, Bergh J, Lluch A, Redfern A, **Chirgwin J**, Lidbrink E, Dhadda A, Lopé z-Vega J, Lindman H, Beith J, Baron-Hay S, Kiermaier A, Herbst F, Ellis I. [P5-22-01] Feasibility and patient safety of serial biopsies (bx) in metastatic HER2-Positive breast cancer to evaluate alterations in molecular biomarkers: Preliminary results of SHERsig (study of HER2 signature in metastatic breast cancer) a prospective phase II study. San Antonio Breast Cancer Symposium, United States, December 2011.

National

Yuen EYN, **Livingston PM**, Batterham R, **Chirgwin J**, Dodson S, Osborne R. Development of a framework for measuring health literacy among caregivers of people with cancer: Insights from concept mapping. COSA-IACR and ANZGOSA Annual Scientific Meeting 2011; Perth, November 2011.

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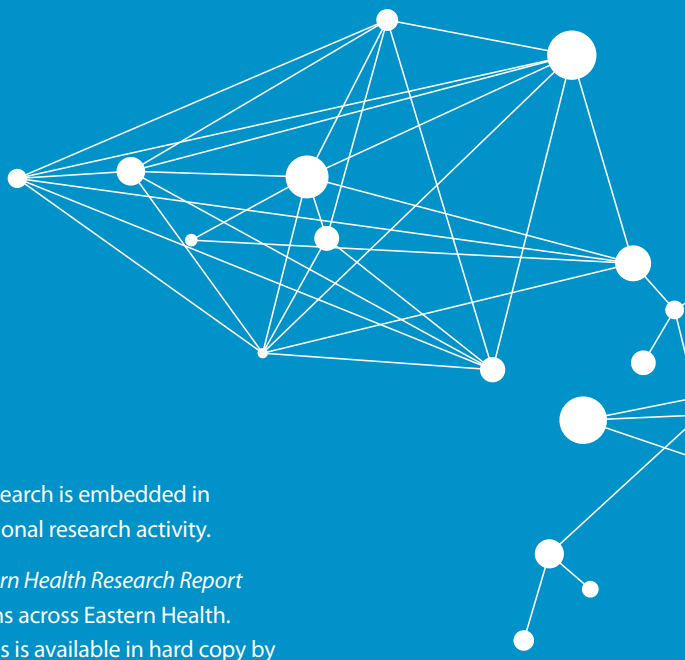

Accessing program reports

Eastern Health is committed to building a culture of research and ensuring such research is embedded in everyday clinical practice. Eastern Health contributes to local, national and international research activity.

The *2012 Eastern Health Research Report* forms part of the broader fifth annual *Eastern Health Research Report* reflecting the high-calibre research, commitment and strength of research programs across Eastern Health. The complete *2012 Eastern Health Research Report* including clinical program reports is available in hard copy by contacting The Office of Research & Ethics on 9895 9551 or via download from **www.easternhealth.org.au**

Readers note: Where projects are collaborative with our respective research partners, Eastern Health staff names are in bold.

Clinical program reports available include (list not exhaustive):

- Eastern Health Clinical School
- Medical student programs
- Research division
- Eastern Clinical Research Unit (ECRU)
- Eastern Clinical Research Unit – Translational Division (ECRU–TRD)
- Turning Point Alcohol & Drug Centre
- Allied Health
- Breast oncology
- Cardiology
- Emergency medicine
- Endocrinology
- Haematology
- Integrated renal and obstetric medicine services
- Intensive care medicine
- Mental health programs
- Neuroscience
- Nursing and midwifery
- Palliative Medicine
- Pharmacy
- Post Graduate Education Unit
- Respiratory and sleep medicine
- Rehabilitation programs
- Rheumatology

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