

Breast cancer clinical trials: Experience in a single Australian institution

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Introduction

- ◇ Health care 50/50 public vs private
- ◇ Traditionally clinical trials conducted in
 - » University-based
 - » Government funded institutions
- ◇ Clinical research in private setting possible
 - » Patient awareness
 - » Supportive services

Introduction

- ◇ Large private hospitals
 - » Equivalent services: Radiology, Pathology
 - » Patient care: Multiple disciplines
- ◇ Funding for research
 - » Pharmaceutical
 - Company sponsored, Investigator-initiated research
 - » Cancer grants: NH&MRC, Cancer council
 - » Cooperative groups

Type of clinical trials

Phase I: Metastatic

- » Resource intensive, After-hours coverage

Phase II: Metastatic / Locally advanced

- » Generally single arm
- » Feasibility assessment essential

Phase III: Early / LABC / Metastatic

- » Maybe registration study, Potential FDA audit
- » Labour-intensive eCRF's, Query response
- » Monitoring

Mount Hospital Clinical Trial Unit (MHCTU)

History

Established 1997-1999

- ◇ Cancer council grant
- ◇ 2 Medical oncologists
⇒ 7 sessions
- ◇ CTU staff
 - » 1 staff = 0.4 FTE

Current 2009

- ◇ Self-sufficient funding
- ◇ 3 Medical oncologists
⇒ 12 sessions
- ◇ CTU
 - » 17 staff: = 12.5 FTE

Infrastructure: Medical

Principal investigator

- » Site specific interest

Members of BCRC (Breast Cancer Research Centre)

- » Radiologist
 - » Pathologist
 - » Breast surgeons
 - » Radiation oncologist
 - » Nuclear physician
 - » Breast nurse
- CTU Manager
Business manager

Infrastructure: CTU

- ◇ CTU Manager
- ◇ Research nurses
- ◇ Data managers
- ◇ Administration officer
- ◇ Ethics officer
- ◇ Project officers
- ◇ Pharmacist trial-dedicated
- ◇ Nursing staff

Essential requirements

- ◇ Clinician commitment
- ◇ CTU staff: Experience & Communication
- ◇ Multidisciplinary team approach
- ◇ Database of patient population
 - » Feasibility, Follow-up
- ◇ Staff, Space, Storage

Prospective data collection

<input type="checkbox"/> F <input type="checkbox"/> S	DOB	Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Dx Status	<input type="checkbox"/>	Dec	726	NoFp <input type="checkbox"/>
	At Dx	At Initial	Recur				Current	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Rx	Endo					Adjuvant chemo			1st Rx Date	<input type="text"/>
Menstrual	<input type="checkbox"/>	Detection	<input type="checkbox"/>	LR_Date	<input type="checkbox"/>	Metastatic	<input type="checkbox"/>	CBC Date	<input type="checkbox"/>		
Menarche	<input type="checkbox"/>	Menopause	<input type="checkbox"/>	G	<input type="checkbox"/>	P	<input type="checkbox"/>	AJ	<input type="checkbox"/>	HRT	<input type="checkbox"/>
				OC	<input type="checkbox"/>	Fhx	<input type="checkbox"/>	Smoker	<input type="checkbox"/>	Alcohol	<input type="checkbox"/>
Date Dx -wrt Mbc	<input type="text"/>						CSF	<input type="text"/>	VitD date	<input type="text"/>	
							Port	<input type="text"/>	Vit D	<input type="checkbox"/>	CYP2d6
Diary Date	<input type="text"/>						LNMP	<input type="text"/>	StatusDx	<input type="text"/>	cm
Last Seen	<input type="text"/>						Resume	<input type="text"/>	Met Status	<input type="text"/>	kg
Today	<input type="text"/>						Amenorr	<input type="text"/>	StatusNow	<input type="text"/>	
GBPS											

Surgery date	<input type="text"/>	<input type="text"/>
Surgery	<input type="text"/>	<input type="text"/>
Pathology	<input type="text"/>	<input type="text"/>
Size	<input type="text"/>	M/Foc <input type="checkbox"/>
Grade	<input type="text"/>	<input type="text"/>
DCIS	<input type="checkbox"/>	LVI <input type="checkbox"/>
ER	<input type="checkbox"/>	PR <input type="checkbox"/>
		HR <input type="checkbox"/>
LN	<input type="checkbox"/>	Tot <input type="checkbox"/>
cerb	<input type="checkbox"/>	ISH <input type="checkbox"/>
Her2+	<input type="checkbox"/>	<input type="checkbox"/>
TMN	<input type="checkbox"/>	TNeg <input type="checkbox"/>
		T1 <input type="checkbox"/>
Stage	<input type="checkbox"/>	CA15_3 <input type="checkbox"/>
NPI	T code <input type="text"/>	N code <input type="text"/>

MBx	<input type="text"/>	<input type="text"/>
ER	<input type="checkbox"/>	<input type="checkbox"/>
PR	<input type="checkbox"/>	<input type="checkbox"/>
Her2	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Mfu	DFI(m): 1st/2nd	PFS
	<input type="text"/>	<input type="text"/>
Months:Dx ?	Mbc	<input type="text"/>
Time to DOD (m)	<input type="text"/>	<input type="text"/>
CNS	<input type="text"/>	<input type="text"/>
From Dx / Mbc / Cns to D	<input type="text"/>	<input type="text"/>

Event	<input type="button" value="Clear events"/>	Trial Potential	<input type="text"/>
<input type="text"/>	<input type="text"/>	Eligible	<input type="checkbox"/>
<input type="text"/>	<input type="text"/>	Trial name	<input type="text"/>
<input type="text"/>	<input type="text"/>	Trial Reg	<input type="text"/>
<input type="text"/>	<input type="text"/>	Drug_Herc	<input type="text"/>
Adjuvant Online			
Nil	<input type="checkbox"/>	FEC, AC-T	<input type="checkbox"/>
Tam	<input type="checkbox"/>	TAC, ddAC-T	<input type="checkbox"/>
AC	<input type="checkbox"/>		

Our experience

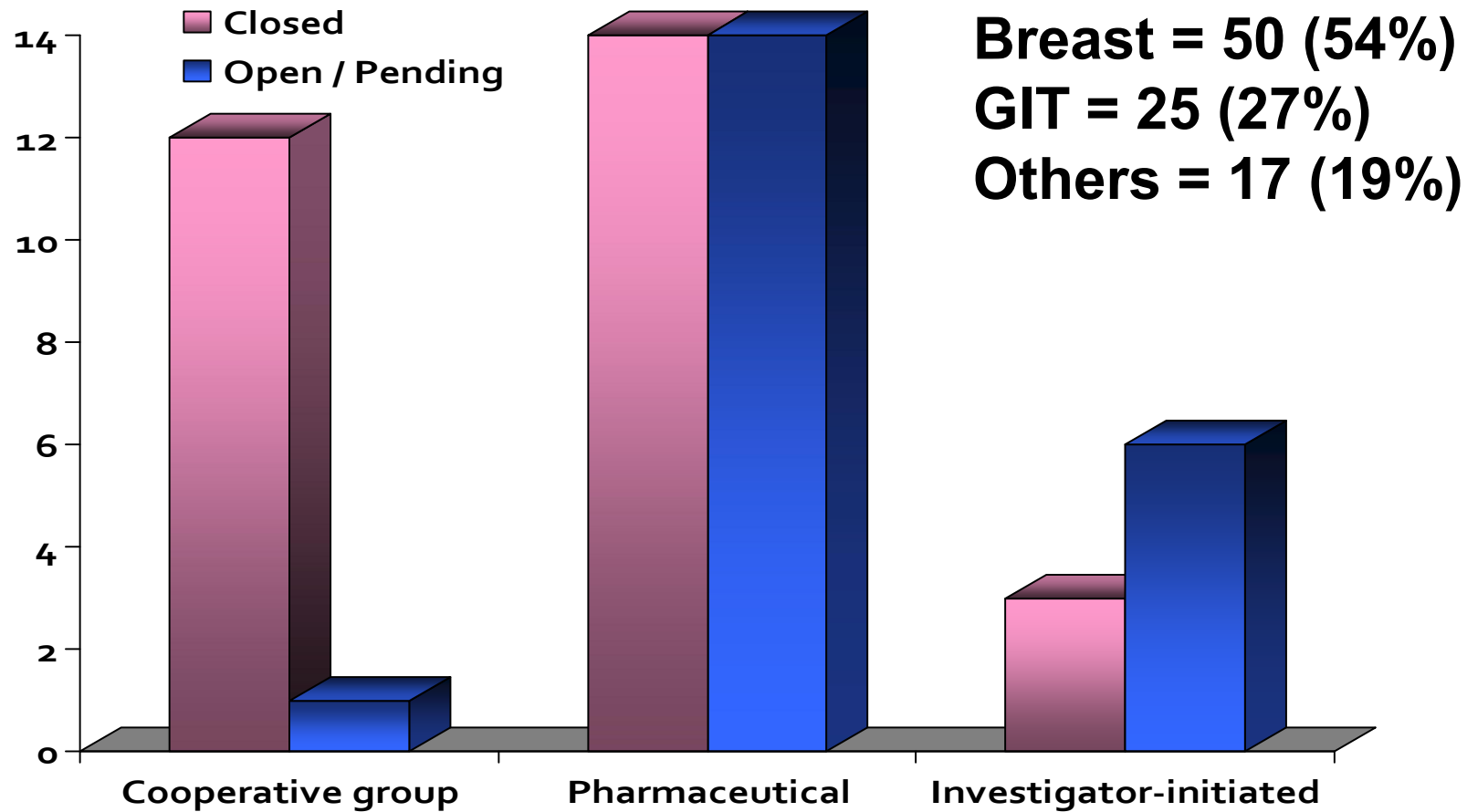
Overview

Tumour site	Patient numbers
Breast	756 (EBC 379, MBC 377)
GIT	159
Lung	23
Melanoma	17
Prostate	12
Hematology	12
	979

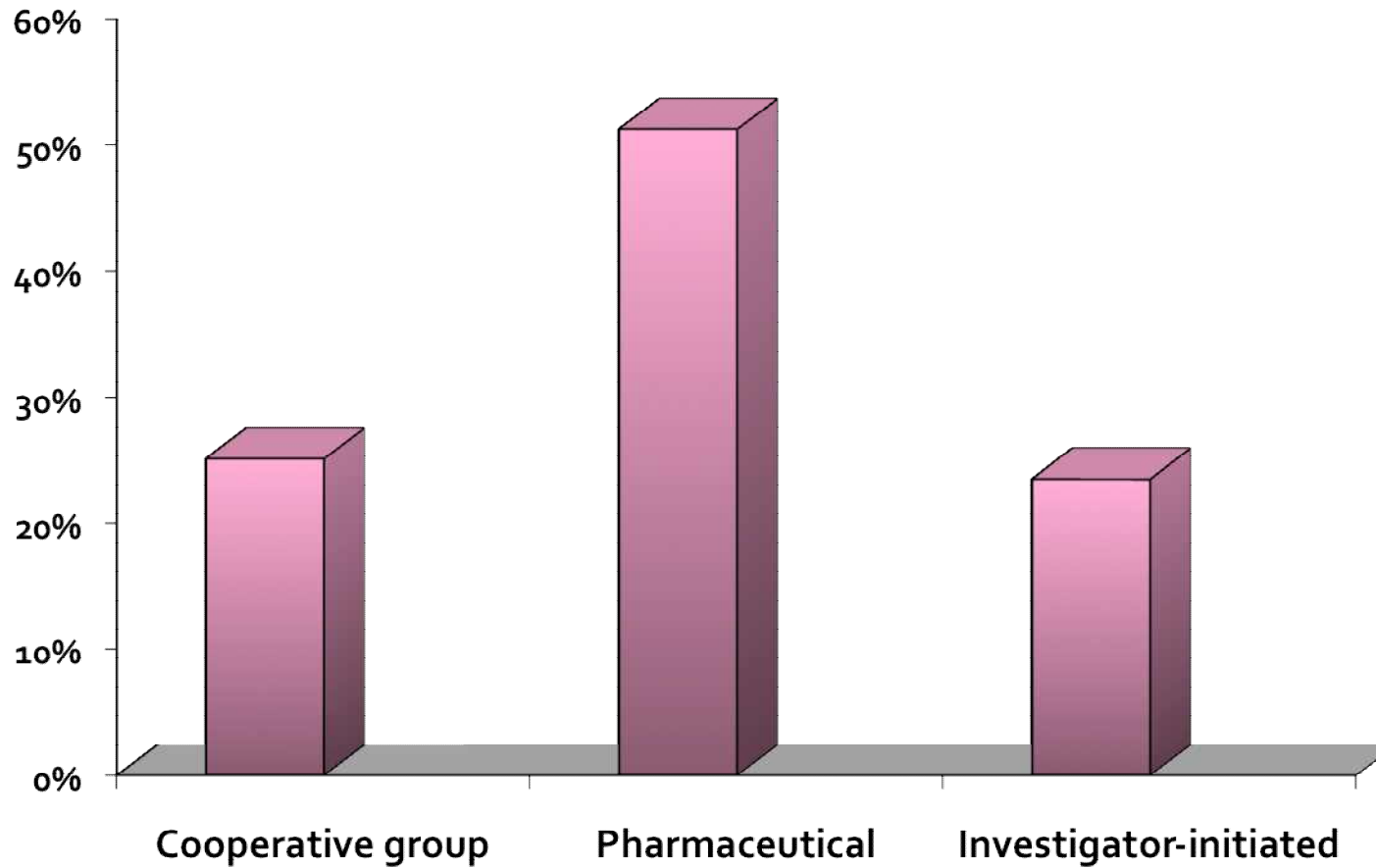
Eligibility n= 724

Recruited	675 (93%)
Did not enter trial	49
Screen failure	2
Non-compliance: All treatment	5
Non-compliance: Trial	42 (5.8%)

Types of trials



Types of trials



Current portfolio: Breast cancer

Adjuvant	Metastatic	Other
BEATRICE	AVERAL	HER2 Discordance *
BETH	Neratinib 3003	STOPP *
BNP *	SHERsig *	Polycar *
Neratinib 3004	CA223	
JUST *	TyN *	
Michelangelo		
Epiphora/Nails *		
Soft		

*Investigator-initiated trials

Current portfolio

Adjuvant

JUST
(Joints under study)

Phase II Randomised placebo-controlled trial to evaluate emu oil for treatment of arthralgias associated with aromatase inhibitor use

Epiphora/Nails

Prevalence of epiphora and nail changes in women with early breast cancer receiving adjuvant docetaxel-based chemotherapy (TAX-AU-6034)

Current portfolio

Metastatic

SHERsig
(MO2204B)

Phase II study to evaluate alterations in molecular biomarkers in HER2-positive metastatic breast cancer together with assessment of trastuzumab use beyond progression

TyN (BCRC101)
Tykerb &
Navelbine

Phase II open label trial of lapatinib and vinorelbine in women with previously treated Her2/neu positive metastatic breast cancer

Current portfolio

HER2 Discordance	Retrospective study of the rate of HER2/neu discordance between primary breast carcinoma and locoregional or metastatic disease
STOPP	Survey of treatment and trial participation in oncology private practice
Polycar	Observational retrospective study of the impact of HER2/neu Ile655Val polymorphism on the incidence of cardiac function decline in patients who have received trastuzumab for HER2/neu positive early breast cancer.

Conclusion

- ◇ Clinical trial conduct in private setting
 - » Infrastructure and recruitment capabilities differs to public institutions
- ◇ Future directions
 - » Under- and Post graduate education / training
 - » National private oncology group conduct of investigator-initiated research