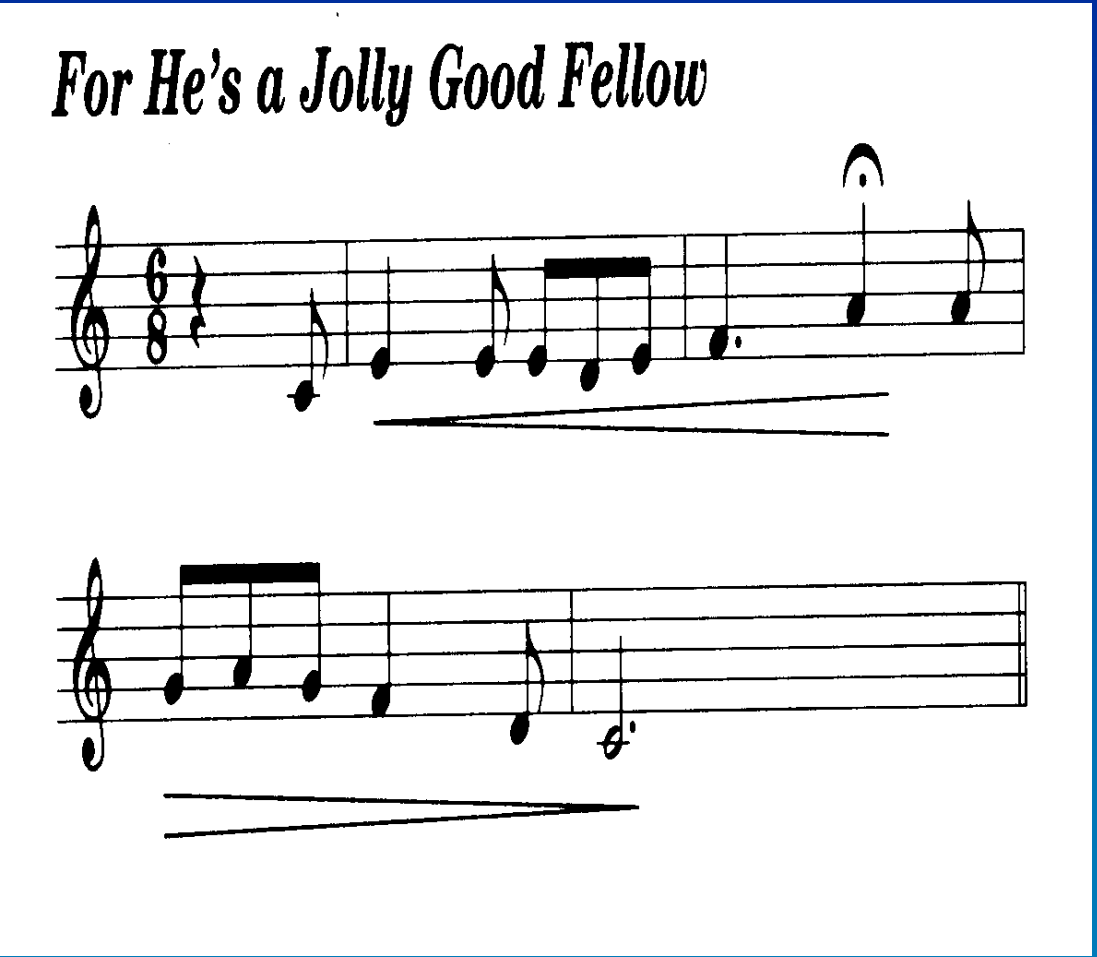
NCIC CTG Overview: A New Investigator's Perspective

Annette Hay, Clinical Trials Fellow

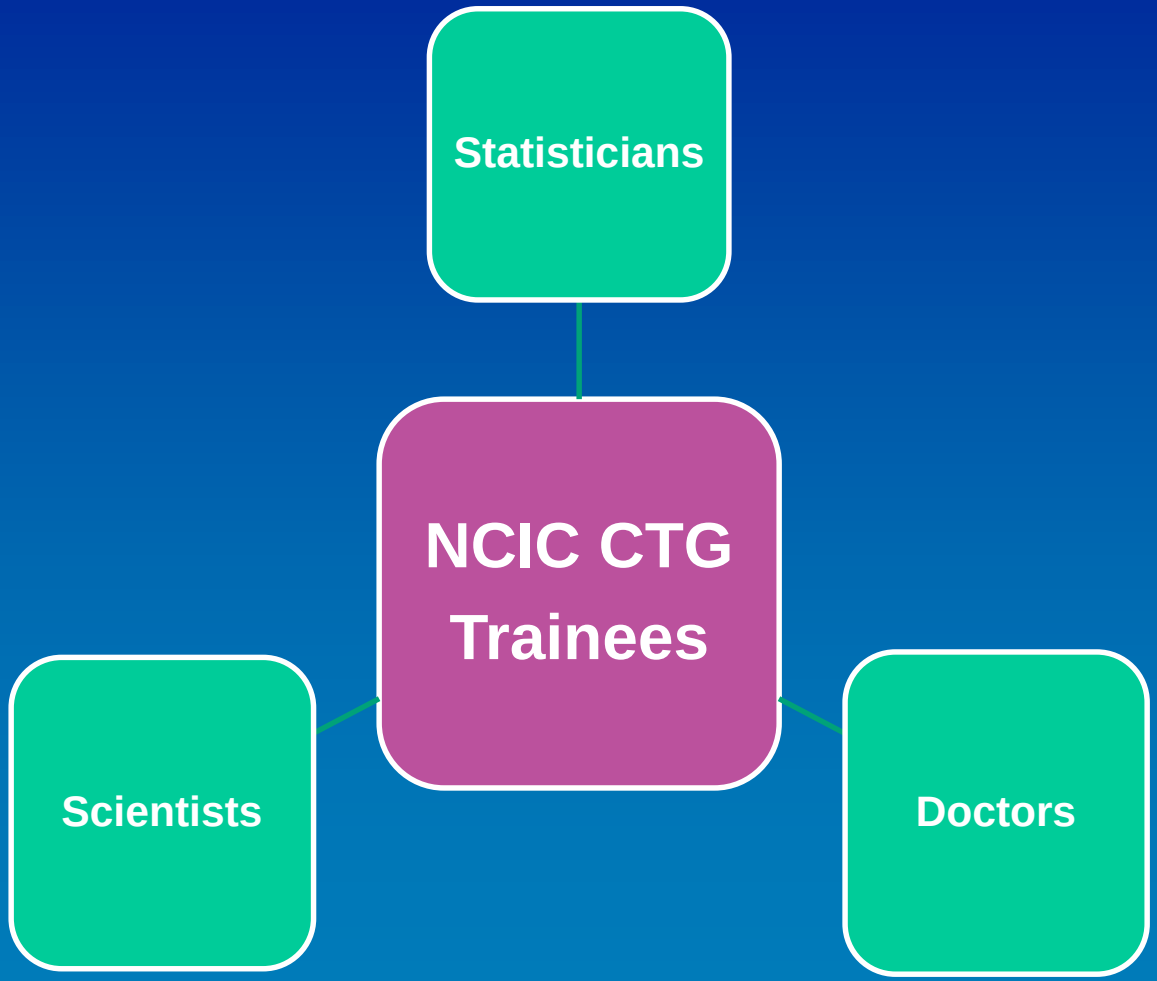
Disclaimer



Objectives

- Demonstrate range of opportunities available
  - Personal experience
  - Sample projects
- Outline processes to answer research question

Phenotype of research trainees I've encountered



Fellowships at NCIC CTG

- Thoracic Oncology Clinical Trials Fellowship
- Drug Development Fellowship
- Astra Zeneca Breast Cancer Fellowship
- OSI Translational Research Fellowship
- Astra Zeneca Clinical Trials Fellowship

Tailored Opportunities

Hematological

- Study development, protocol writing, phase I (LY.15)
- Data review, analysis, manuscript writing, phase III (LY.12)
- Economic analysis (LY.12)
- Collaboration with Germans in Hodgkin Lymphoma (HD.6)
- Editorial & review articles
- Clinical work

Tailored Opportunities

Methodological

- **Community Health and Epidemiology MSc**
  - **Controlled clinical trials**
  - **Health economics**
  - **Health policy**
- **Predictive value of phase II trial designs**
- **Apprenticeship**

Secondary analyses

- Clinical trial enrolment first priority
- Opportunities for secondary analyses
  - Comparative
  - Database interrogation
  - Correlative science
  - Methodological: economics, statistical . . .

An Individual Patient-Data Comparison of German Hodgkin Study Group HD10 and HD11 Combined Modality Therapy and NCIC Clinical Trials Group HD.6 ABVD Alone

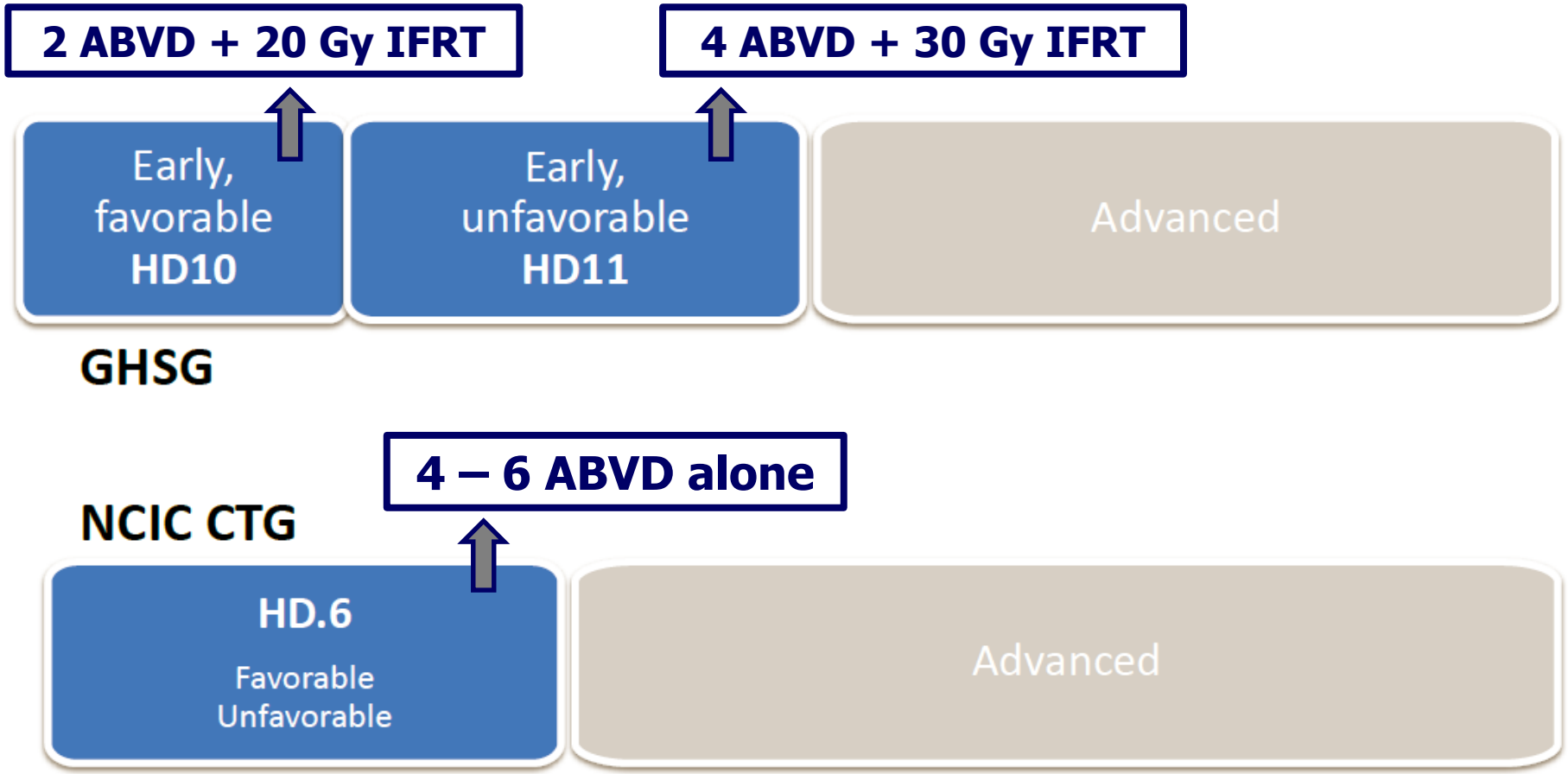
Hay AE, Klimm B, Chen BE, Goergen H, Shepherd LE, Fuchs M, Gospodarowicz M, Borchmann P, Connors JM, Markova J, Crump M, Lohri A, Winter JN, Dorken B, Pearcey RG, Diehl V, Horning SJ, Eich HT, Engert A, Meyer RM

GHSG German Hodgkin Study Group

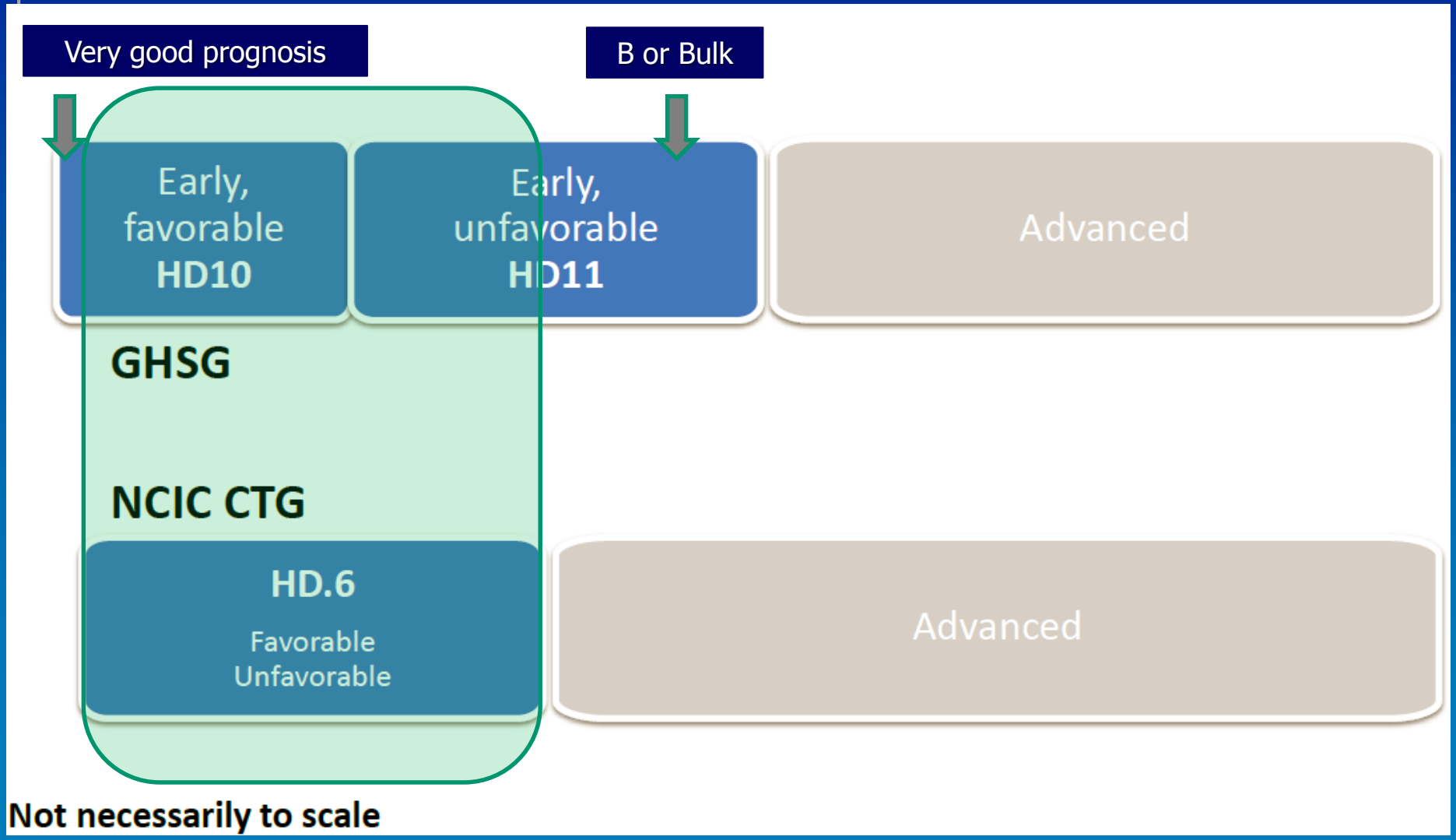
NCIC Clinical Trials Group
NCIC Groupe des essais cliniques

Eastern Cooperative Oncology Group

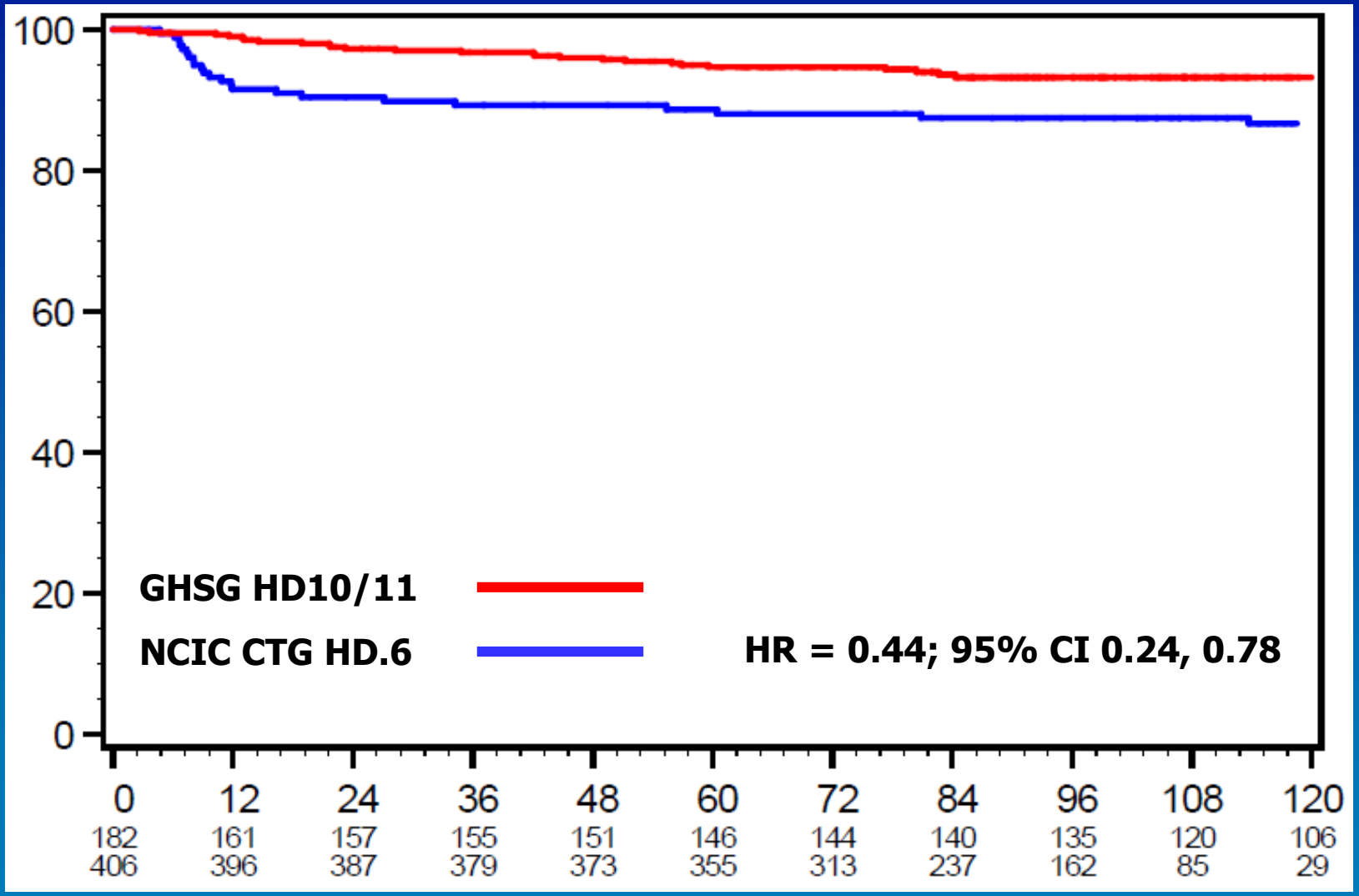
Individual Patient Data Comparison
Limited-stage Hodgkin Lymphoma



Individual Patient Data Comparison
Limited-stage Hodgkin Lymphoma



Radiation improves disease control . .



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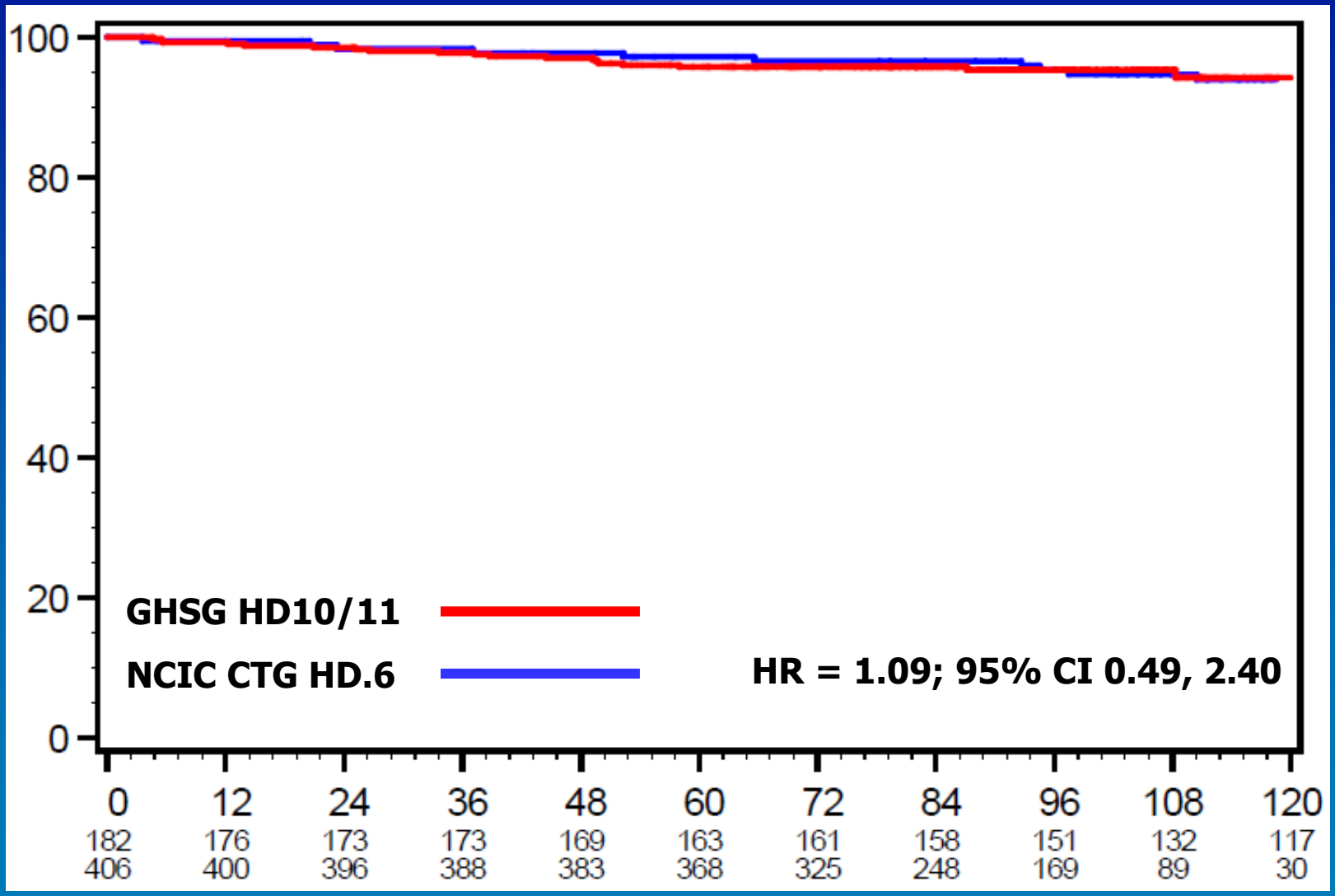
Hay *et al*, abstract 548, ASH 2012

No difference in survival at 8 years



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Hay *et al*, abstract 548, ASH 2012

Location of colon cancer (right-sided versus left-sided) as a predictor of benefit from cetuximab in NCIC CTG CO.17

Stephanie Y. Brulé, Derek J. Jonker, Christos Stelios Karapetis, Christopher J. O'Callaghan, Malcolm J. Moore, Ralph Wong, Niall C. Tebbutt, Craig Underhill, Desmond Yip, John Raymond Zalcberg, Dongsheng Tu, Rachel Anne Goodwin

Database interrogation

NCIC CTG CO.17

- **Cetuximab versus best supportive care in pre-treated metastatic colon cancer, Jonker 2007**

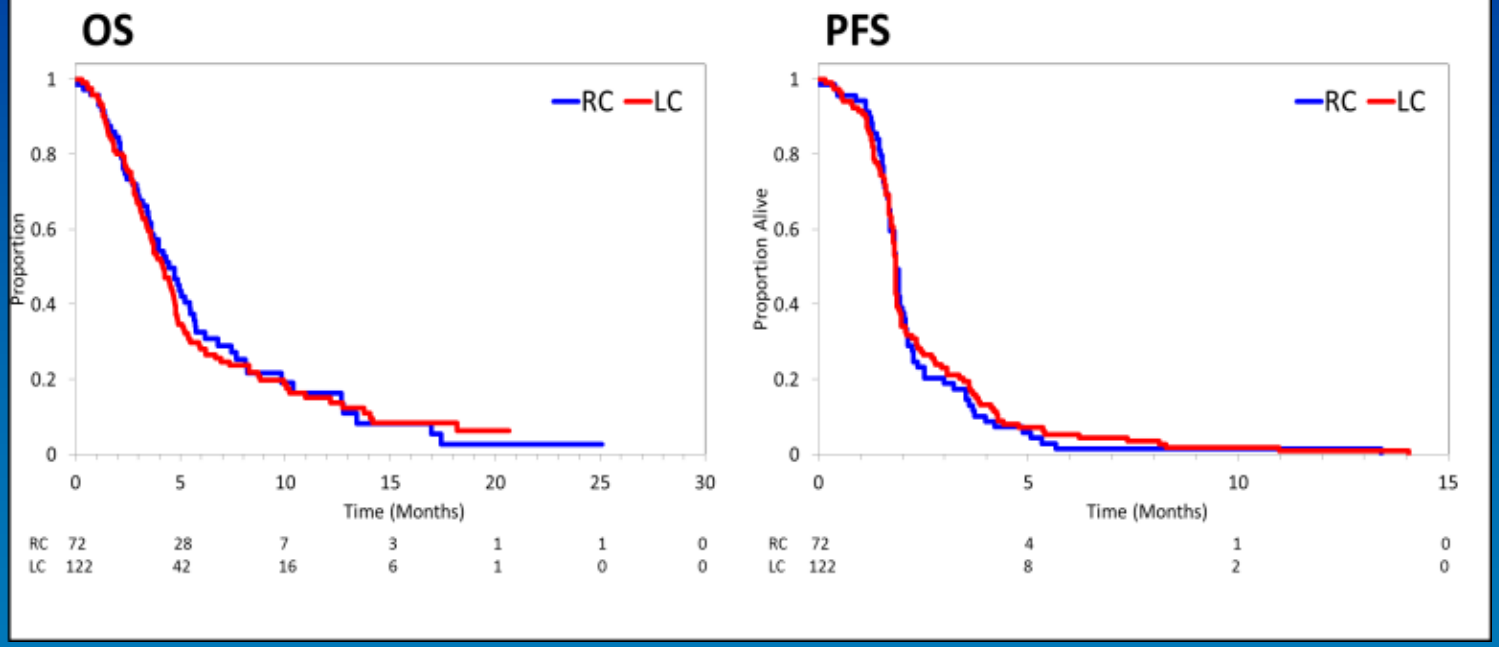
Study question

- **In this population is primary tumour site (right vs. left) prognostic for outcome or predictive of benefit from cetuximab therapy?**

Brule *et al*, abstract 3528, ASCO 2013

Tumour site is not prognostic . .

Figure 1. Location of the primary (RC vs LC) is not prognostic: OS and PFS by tumour location in patients on BSC alone



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Brule *et al*, abstract 3528, ASCO 2013

but is predictive of benefit from cetuximab

	KRAS WT subset	Median survival (months) CET vs BSC	Benefit CET vs. BSC HR (95% C.I.), p value	Predictive effect Interaction p value
OS	RC	6.2 vs 3.5	0.66 (0.36, 1.21), p=0.18	0.25
	LC	10.1 vs 4.8	0.49 (0.31, 0.77), p=0.002	
PFS	RC	1.9 vs 1.9	0.73 (0.42, 1.27), p=0.26	0.002
	LC	5.4 vs 1.8	0.28(0.18, 0.45), p<0.0001	

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Brule *et al*, abstract 3528, ASCO 2013

Exploratory analysis of angiotensin converting enzyme and aldosterone serum levels as prognostic and predictive biomarkers on the NCIC CTG BR24 trial

Jair Bar, Keyue Ding, Huijin Zhao, Scott Laurie, Lei Han, Frances Shepherd, Christina Addison, Glenwood Goss, Jim Dimitroulakos, Penelope Bradbury

Correlative science

BR.24
Advanced non-small cell lung cancer
296 patients

Carboplatin & paclitaxel

Carboplatin, paclitaxel & cediranib

Cediranib: VEGF inhibitor

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Goss *et al*, JCO 2009

Correlative science

- **Benefit from angiogenesis inhibitors has been linked to high blood pressure**
- **Exploratory analysis of angiotensin converting enzyme (ACE) and aldosterone (ALD) serum levels as prognostic and predictive biomarkers**
- **ACE and Ald levels retrospectively tested on 226 baseline serum samples**

Bar *et al*, abstract 8048, ASCO 2013

High serum ACE level may be prognostic

High ACE level (≥ 115 ng/ml)

- **Associated with better performance status (p=0.03)**
- **Longer overall survival (HR 0.52, p=0.025)**

Bar *et al*, abstract 8048, ASCO 2013

High serum ACE level may be prognostic

High ACE level (≥ 115 ng/ml)

- **Associated with better performance status (p=0.03)**
- **Longer overall survival (HR 0.52, p=0.025)**

Low ACE may predict benefit from cediranib

Low serum ACE level (< 115 ng/ml)

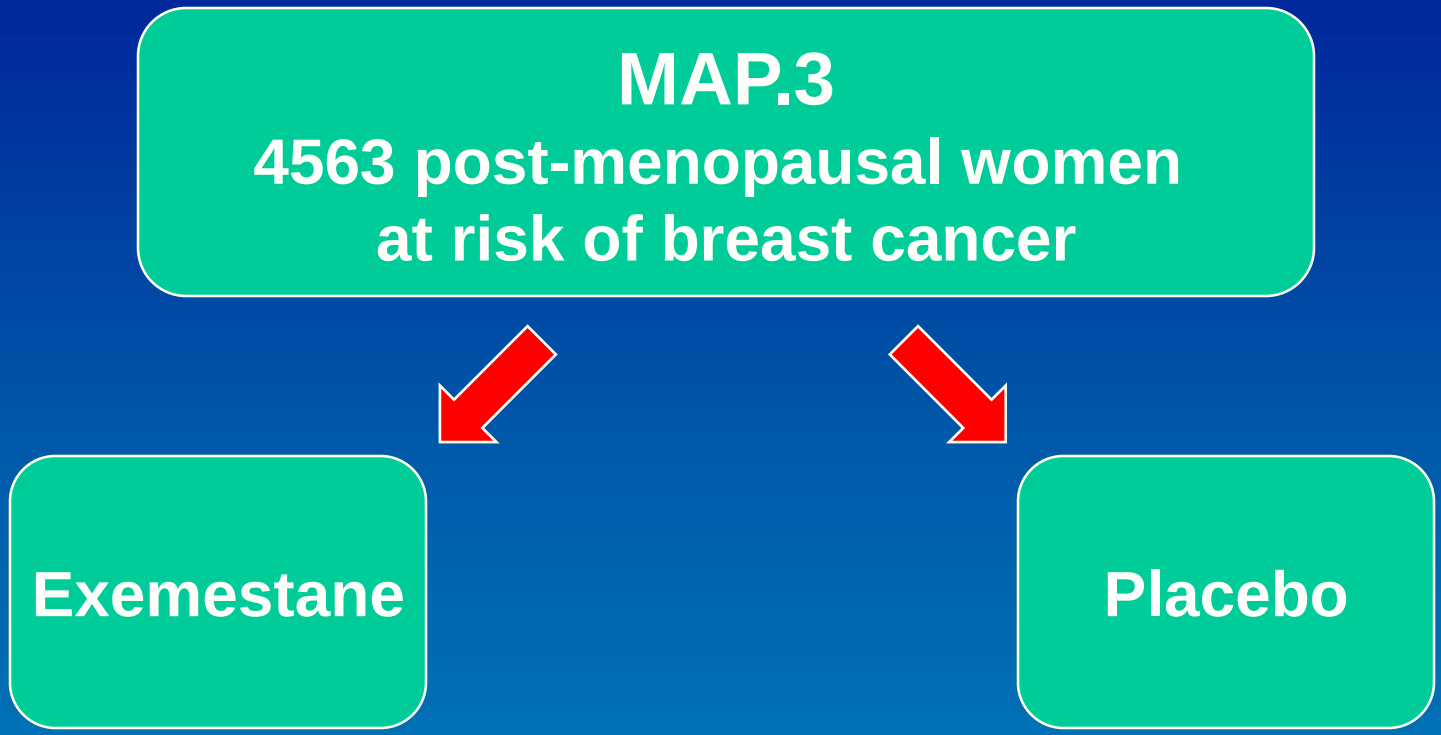
- **Improved overall survival with addition of cediranib to PC (HR 0.64, p=0.03)**

Bar *et al*, abstract 8048, ASCO 2013

NCIC CTG MAP.3: Symptoms and quality of life among racial/ethnic minority women taking the aromatase inhibitor exemastane for breast cancer risk reduction

Beverley Moy, Dongsheng Tu, Harriet Richardson, Elizabeth Maunsell, Paul Goss

Quality of life



Canada, USA, Spain & France

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Goss *et al*, NEJM 2011

Racial/ethnic minority women experience fewer adverse events on aromatase inhibitors

Ethnic minority compared with white women

- **Fewer sweats (12% vs. 22%, p=0.005)**
- **Less vaginal dryness (8% vs. 16%, p=0.03)**

Moy *et al*, abstract 6557, ASCO 2013

Racial/ethnic minority women experience fewer adverse events on aromatase inhibitors

Hispanic women compared with non-Hispanic experienced significantly less frequent

- Hot flashes
- Fatigue
- Sweats
- Insomnia
- Heartburn
- Arthritis
- Nausea
- Depression
- Back pain
- Cough
- Vaginal dryness

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Moy *et al*, abstract 6557, ASCO 2013

How to do it too

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ABOUT US

The NCIC Clinical Trials Group is a cooperative oncology group which carries out clinical trials in cancer therapy, supportive care and prevention across Canada and internationally. It is one of the national programmes and networks of the Canadian Cancer Society Research Institute (CCSRI), and is supported by the Canadian Cancer Society (CCS).

The information contained in this website is intended for use by NCIC Clinical Trials Group members at participating centres. If you are a cancer patient, your doctor can explain how this information applies to you, or you can call the Cancer Information Service of the Canadian Cancer Society at 1-888-939-3333.

We are located at Queen's University, Kingston Ontario at the Cancer Research Institute.

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Public Listings

Information for New Centre Staff

A descriptive listing of all current trials is provided:

Phase III Site Committee Trials
- Accrual: Phase III - Closed Studies

Investigational New Drug (IND) Program Trials
- Accrual: IND Trials - Closed Studies

For Members Only (full study information)

Members

Single Study Members

Investigational New Drug Studies

PHASE II STUDIES

Brain - I142 I204
Breast - I163 I164 I197 I213
Cervix - I184 I199
Chronic Lymphocytic Leukemia - I193
Colon - I146 I210
Endometrial (non-sarcomatous uterine c.) - I148 I160 I192
Fallopian Tube - I185
Head and Neck - I157
Liver (hepato-cellular) - I168
Lung Cancer - Non-Small Cell - I211
Melanoma - I156 I169 I189 I202
Mesothelioma - I183 I207
Multiple Myeloma - I145 I191
Multiple Sites - I206
Non-Hodgkins Lymphoma - I150 I152 I172 I182 I194
Ovary - I149 I185
Prostate - I165 I167 I195 I205 I209
Renal (kidney) - I161
Sarcoma - soft tissue - I155 I200

PHASE I STUDIES

Acute Myeloid Leukemia - I141
Brain - I162
Colon - I171 I175 I187
Lung Cancer - Non-Small Cell - I171 I175 I215
Multiple Sites - I130 I134 I144 I147 I154 I178 I188 I203
Myelodysplastic Syndrome - I141
Neuroblastoma - I212
Prostate - I153
Rectal - I187
Unknown or unspecified malignancy - I166 I166B I177 I179 I181

PHASE I-II STUDIES

Acute Myeloid Leukemia - I186
Brain - I170
Breast - I198
Colon - I208 I214
Lung Cancer - Non-Small Cell - I196 I214
Lung Cancer - Small Cell (= oat cell) - I190
Myelodysplastic Syndrome - I186
Pancreas - I173

IND. 209

I209

A Randomized Phase II Study of Reolysin in Combination With Docetaxel and Prednisone or Docetaxel and Prednisone Alone in Patients With Metastatic Castration Resistant Prostate Cancer

Eligibility: Patients with a histological diagnosis of metastatic and/or locally recurrent castration resistant adenocarcinoma of the prostate. Tumour block available. Patients must be hormone refractory and have discontinued anti-androgens for at least 4 weeks prior to study entry. PSA >= 5 ng/mL at study entry. No prior chemotherapy for recurrent/metastatic disease. No prior docetaxel unless given adjuvantly and >= 12 months prior to enrollment. ECOG 0, 1 or 2. Adequate end-organ function.

Objectives: 1. To evaluate efficacy which will be based on the lack of disease progression measured at 12 weeks. 2a. To determine the tolerability and toxicity of Reolysin® and docetaxel when given in combination. 2b. To investigate additional potential measures of efficacy including CTC status, CTC conversion rate, change in PSA levels, Objective response rate and effect of both treatments on overall survival. 2c. Explore potential molecular factors predictive of response in archival tumour and baseline CTCs.

NCT Registration ID (from clinicaltrials.gov): NCT01619813
Participant: Limited to invited cancer centres only.

Status: Open
Activation Date: June 11, 2012

Chairs: (Canada) Dr. Bernhard Eigl, BCCA - Vancouver Cancer Centre, 1(604) 877-6000 Ext. 2707

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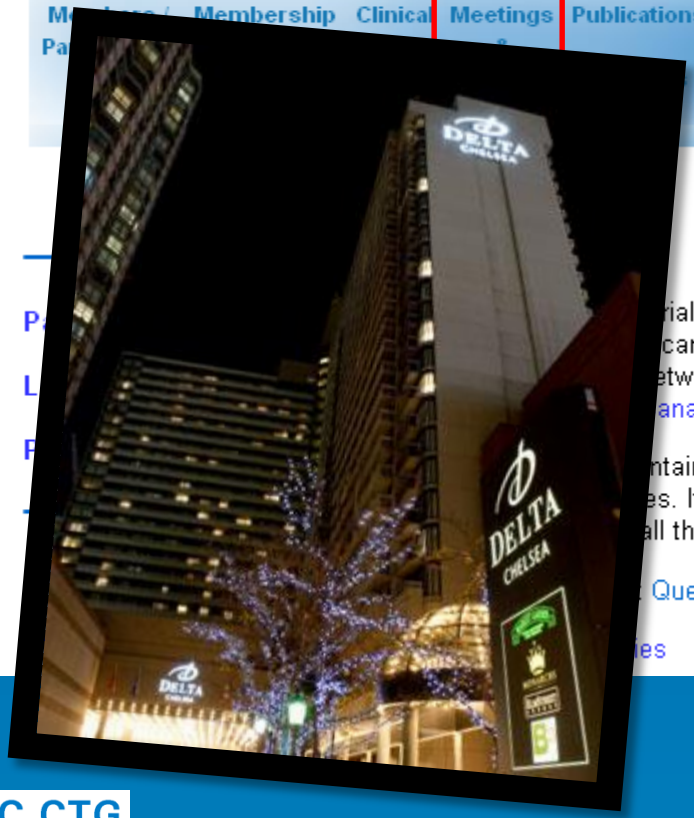
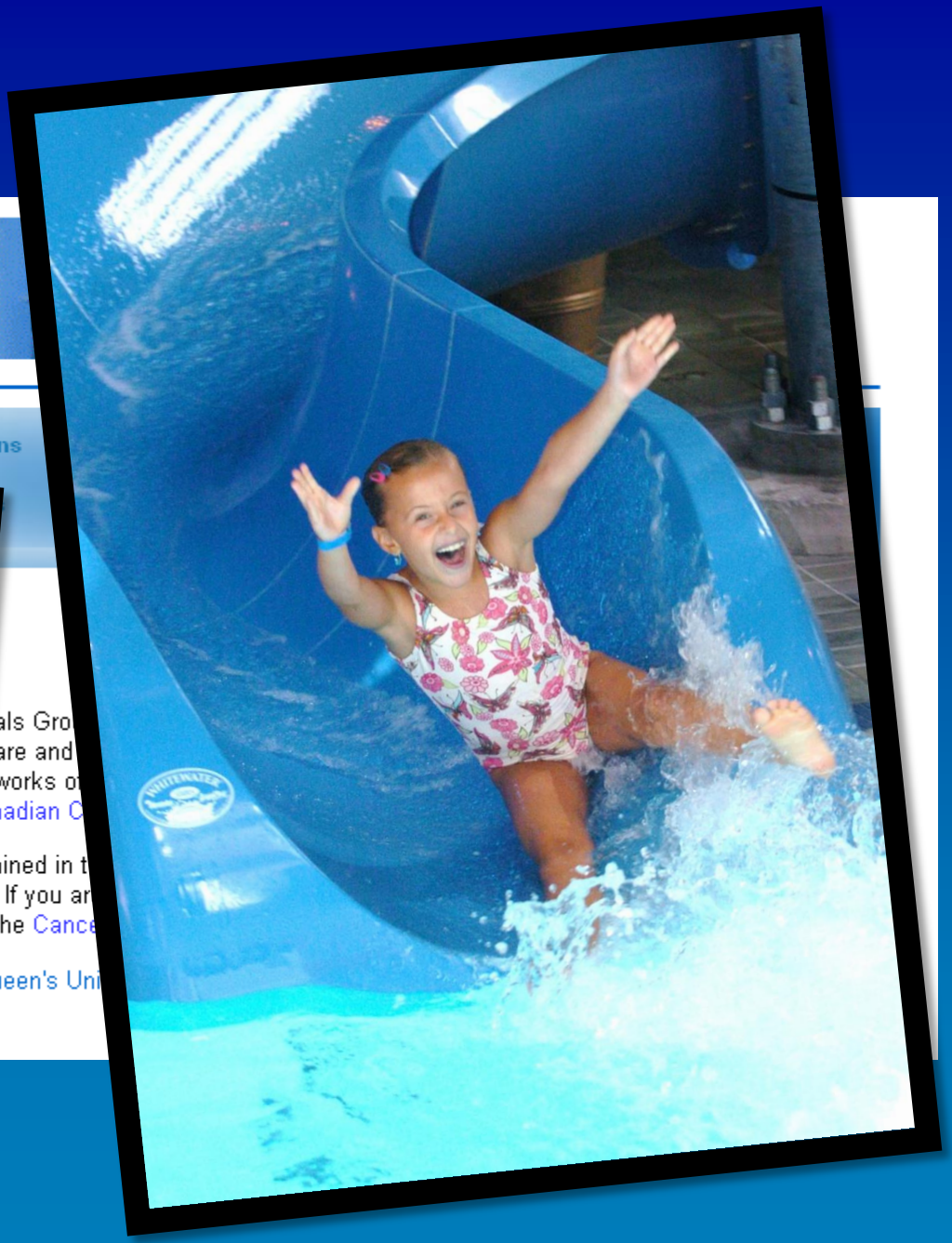
Membership Clinical Meetings Publications





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NCIC CTG GROUP PUBLICATIONS & PRESENTATIONS

NCIC CTG Abstracts presented at the 2013 ASCO Annual Meeting

Chicago, Illinois
May 31 - June 4, 2013

NCIC CTG Abstracts presented at the
35th Annual San Antonio Breast Cancer Symposium

Henry B. Gonzalez Convention Center
San Antonio, Texas
December 4-8, 2012

NCIC CTG Abstracts presented at the
54th ASH Annual Meeting and Exposition

Georgia World Conference Center
Atlanta, GA
December 8-11, 2012

NCIC CTG Primary Publications

Journals

Abstracts

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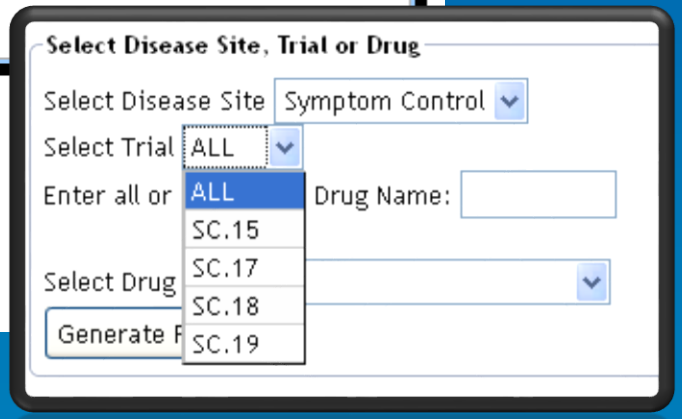

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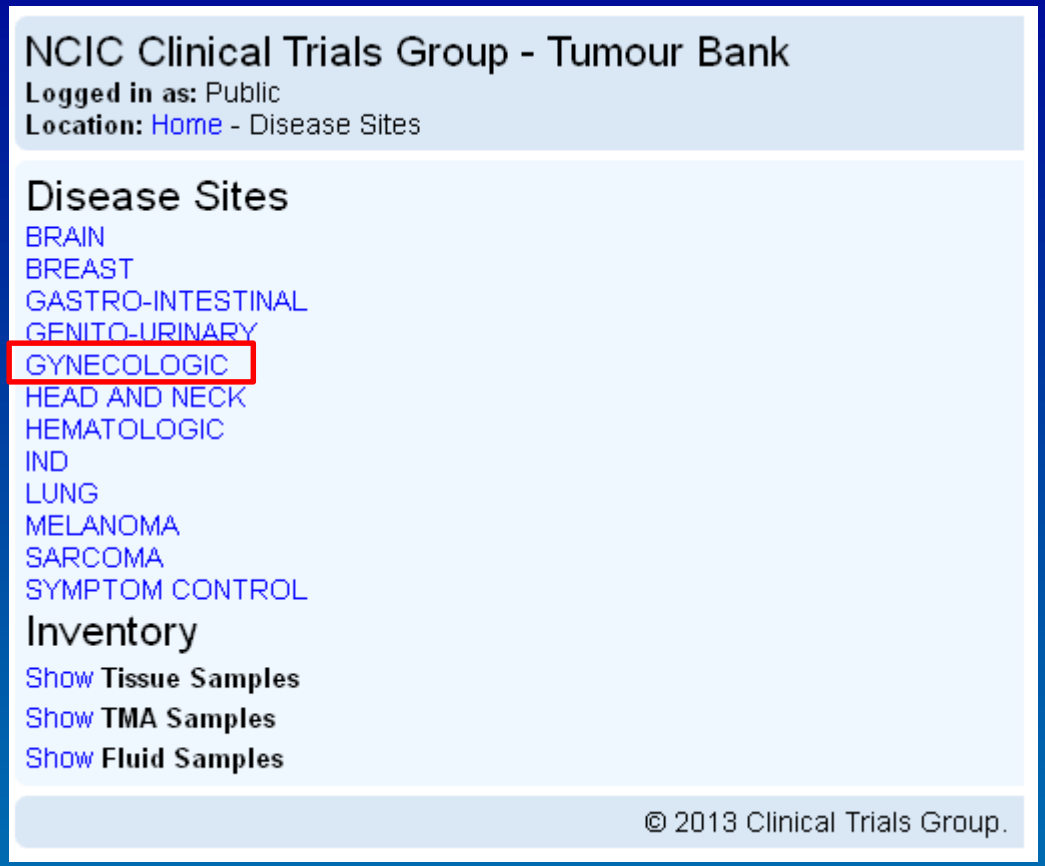
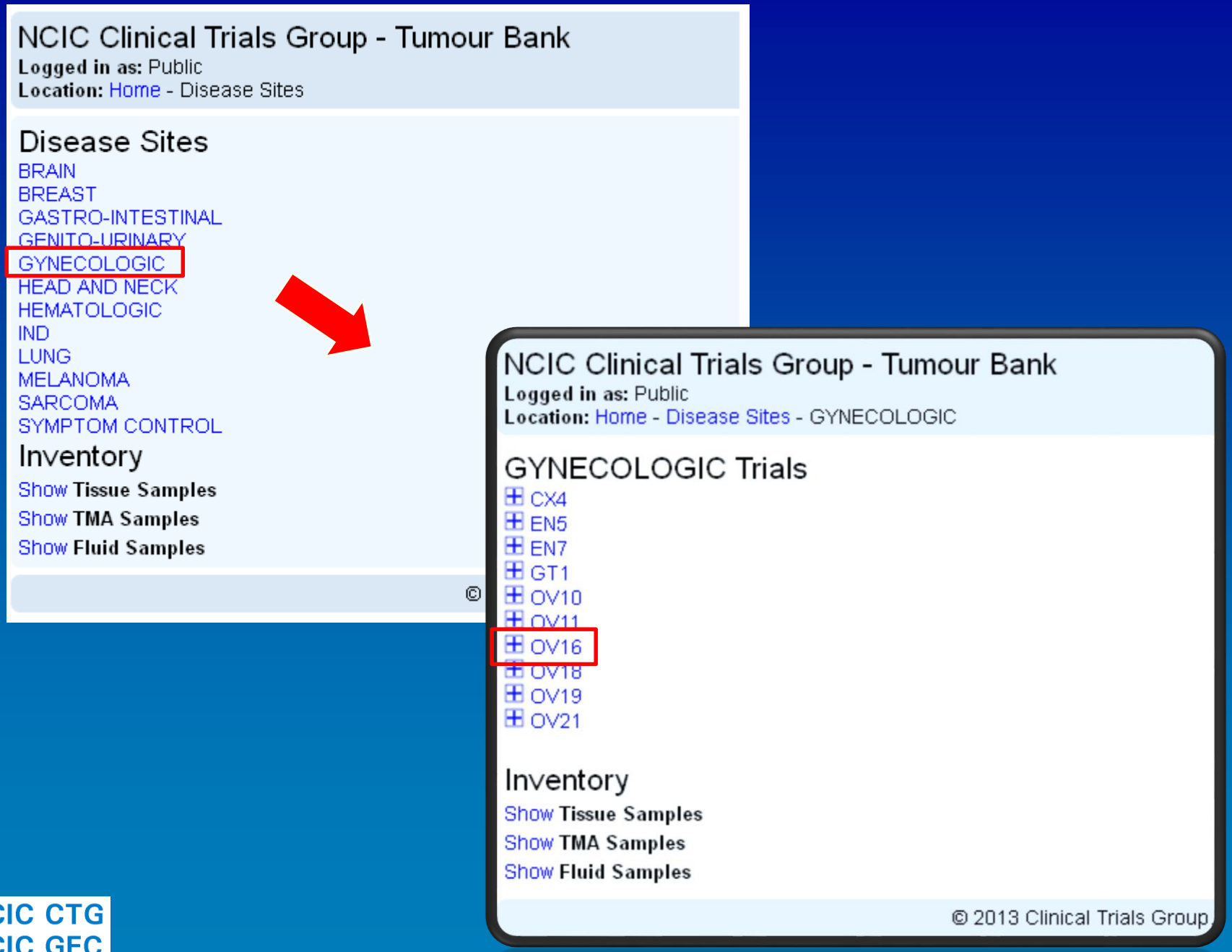
Correlative Science / Tumour Bank

The NCIC Clinical Trials Group (NCIC CTG) established the Tumour Tissue Data Repository (TTDR) in 1997 to support Correlative Science with the assistance of Rhone Poulenc Rorer (now Sanofi-Aventis). The NCIC CTGTTDR contains unique disease specific collections which are linked to an associated clinical dataset. This represents a "real" tumour bank in that tissue is collected from institutions across Canada and the world, catalogued and housed centrally in the Department of Pathology and Molecular Medicine at Queen's University.

Our Mission


NCIC Clinical Trials Group - Tumour Bank
Logged in as: Public
Location: Home - Disease Sites
Disease Sites
BRAIN
BREAST
GASTRO-INTESTINAL
GENITO-URINARY
GYNECOLOGIC
HEAD AND NECK
HEMATOLOGIC
IND
LUNG
MELANOMA
SARCOMA
SYMPTOM CONTROL
Inventory
Show Tissue Samples
Show TMA Samples
Show Fluid Samples
© 2013 Clinical Trials Group.



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OV16 Details

Status: Closed
Activation Date: 2001AUG31
Closing Date: 2005JUN29
Phase: III

Description: A Phase III Study of Cisplatin Plus Topotecan Followed by Paciltaxel plus Carboplatin versus Paclitaxel plus Carboplatin as First Line Chemotherapy in Women with Newly Diagnosed Advanced Epithelial Ovarian Cancer

Eligibility: Patients with confirmed epithelial ovarian (or primary fallopian or peritoneal) cancer, Stage IIB to IV, with microscopic or macroscopic residual disease who have not received prior chemotherapy and have evidence of adequate organ function.

Objective: Primary: to compare progression free survival. Secondary: to compare overall survival, response rates, toxic effects, quality of life, and CA 125 normalization rates.

Participation: Not limited

Lay Description: The main purpose of this research study is to find out if first line treatment with four cycles of cisplatin combined with topotecan followed by another four cycles of paclitaxel combined with carboplatin will cause the tumour to shrink at least as well as, if not better than, standard treatment of paclitaxel combined with carboplatin given for eight cycles.

Publications Show

Inventory

Hide **Tissue Samples**

Disease Site	Trial Code	Patients Accrued	Patients - Blocks	Patients - Slides	Patients - Blocks and/or Slides
GYNECOLOGIC	OV16	819	315	325	364

Hide **TMA Samples**
(Core size is 0.6 mm)

Disease Site	Trial Code	Patients Accrued	TMA Blocks	Patients on TMA Blocks
GYNECOLOGIC	OV16	819	7	248

Hide **Fluid Samples**

Disease Site	Trial Code	Patients Accrued	Patients - Whole Blood	Patients - Cellular Component of Blood	Patients - DNA extracted from Blood	Patients - RNA extracted from Blood	Patients - Plasma	Patients - Serum	Patients - Urine	Patients - Buccal
GYNECOLOGIC	OV16	819	0	0	0	0	0	0	0	0

Process

- Draft brief protocol
  - Study question
  - Rationale
  - Data required to answer
  - Proposed methods
- Revise with central office input
- Obtain appropriate approval
- Follow processes

Potential Challenges

Question is not appropriate for CTG databases

- **Data not collected**
- **Data not available in appropriate format**
- **Timing of analysis not appropriate**

Potential Challenges

Question is not appropriate for CTG databases

- Data not collected
- Data not available in appropriate format
- Timing of analysis not appropriate

Resources

- Personnel
- Funding

Potential Challenges

Approval processes required

- **Trial team, study chair, disease site committee**
- **REBs (Queen's and host institution)**
- **Pharma**

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