



Clinical
Oncological
Society of
Australia

Tissue banking for cancer clinical trials

**Outcomes from a COSA workshop
(and a personal view)**

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COSA

- The peak clinical body representing all providers of cancer care.
- mission: to develop and maintain high-quality clinical care of cancer patients in Australia.
- COSA members are doctors, nurses, scientists and all types of allied health professionals involved in clinical care of cancer patients
- objectives include:
 - promotion, facilitation and dissemination of research in all areas of cancer control

Cancer Cooperative Trials Groups

- Australia and New Zealand Melanoma Trials Group (ANZMTG)
<http://www.anzmtg.org/>
- Australian New Zealand Breast Cancer Trials Group (ANZBCTG)
<http://www.anzbctg.org/>
- Australia New Zealand Germ Cell Trials Group (ANZGCTG)
http://www.ctc.usyd.edu.au/trials/cancer/germ_cell.htm
- Australia New Zealand Children's Haematology and Oncology Group (ANZCHOG)
<http://www.cancercouncil.com.au/editorial.asp?pageid=508>
- Trans-Tasman Radiation Oncology Group (TROG)
<http://www.trog.com.au/>
- Australasian Lung cancer Trials Group (ALTG)
<http://www.altg.com.au/pages/home.php>

Cancer Cooperative Trials Groups

- Australia New Zealand Gynaecological Oncology Group (ANZGOG) <http://www.anzgog.org.au/>
- Australasian Leukaemia & Lymphoma Group (ALLG) <http://www.petermac.org/allg/>
- Australasian Gastrointestinal Trials Group (AGITG) <http://www.gicancertrials.org.au/>
- Australian Prostate and Urogenital Cancer Group (APUG)
- Co-operative Trial Group for Neuro-Oncology (COGNO)
- Psycho-Oncology Cooperative Research Group (PoCoG) <http://www.pocog.org.au/>
- Australia Sarcoma Study Group (ASSG).

**NHMRC-funded Enabling Project 2005-10
- Clinical Trials Resources:**

**“Protocol development, web based
data collection and quality
assurance for all Cancer
Cooperative Trials Groups”**

COSA and 13 Cooperative Trials Groups

Aim

- to enhance the capacity of all member Cooperative Trials Groups (CTGs) of COSA to conduct high quality clinical research by developing and providing fundamental resources in 4 areas:
 - **Protocol development** from concept outline to externally approved protocol
 - **Information systems**: web based randomisation and data collection.
 - **Quality assurance**: independent, comprehensive program.
 - **Standardised operating procedures**

2007-8 Additional Initiatives

- Clinical Trial Insurance and risk assessment
- Executive Officer's Network
- Costing of clinical trials
- Education of trial coordinators, nurses, doctors, others
- Tissue banking

Background

- Increasing interest in biomarkers
 - Predict response to treatment
 - Prognostic value
 - Markers of underlying disease
- Trials often include a biological sub-study
- Need to link tissue banks to cancer clinical trials:
 - Opportunity for more targeted Rx approaches
 - Maintain Australia's research competitiveness

Linking cancer trials with biobanks

- Predominantly undertaken by pharmaceutical industry
 - Blood samples for pharmacogenomic research
 - Off-shore analysis
- Some activity by the Cooperative Cancer Clinical Trials Groups
- Typically samples collected for one trial
- No systematic approach for multi-site studies

Current biobanks

- Number of biobanks across Australia
- Several collaborations established:
 - Australian Biospecimen Network (ABN)¹
 - National Leukaemia & Lymphoma Tissue Bank (NLLB)¹
 - Breast Cancer Biospecimen Resource
 - Australian Prostate Cancer Collaboration (APCC) Bioresource
 - Victorian Cancer Biobank Consortium (VCBC)¹
 - Australian Ovarian Cancer Study (AOCS)¹

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K-ras Mutations and Benefit from Cetuximab in Advanced Colorectal Cancer

Christos S. Karapetis, M.D., Shirin Khambata-Ford, Ph.D., Derek J. Jonker, M.D., Chris J. O'Callaghan, Ph.D., Dongsheng Tu, Ph.D., Niall C. Tebbutt, Ph.D., R. John Simes, M.D., Haji Chalchal, M.D., Jeremy D. Shapiro, M.D., Sonia Robitaille, M.Sc., Timothy J. Price, M.D., Lois Shepherd, M.D.C.M., Heather-Jane Au, M.D., Christiane Langer, M.D., Malcolm J. Moore, M.D., and John R. Zalcberg, M.D., Ph.D.*

ABSTRACT

BACKGROUND

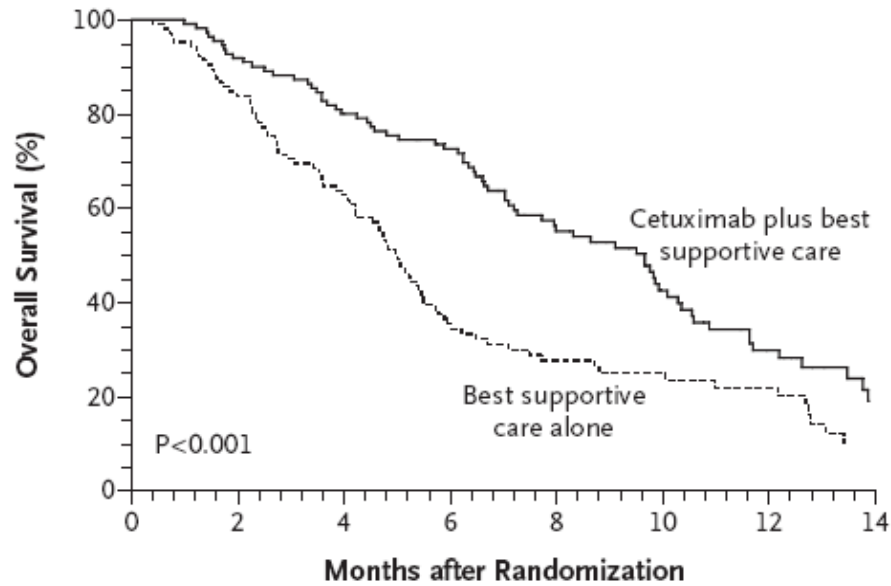
Treatment with cetuximab, a monoclonal antibody directed against the epidermal growth factor receptor, improves overall and progression-free survival and preserves the quality of life in patients with colorectal cancer that has not responded to chemotherapy. The mutation status of the *K-ras* gene in the tumor may affect the response to cetuximab and have treatment-independent prognostic value.

From Flinders Medical Centre and Flinders University, Adelaide, Australia (C.S.K.); Bristol-Myers Squibb Research and Development, Princeton, NJ (S.K.-F.); Ottawa Hospital Research Institute, University of Ottawa, Ottawa (D.J.J.); National Cancer Institute of Canada Clinical Trials Group,



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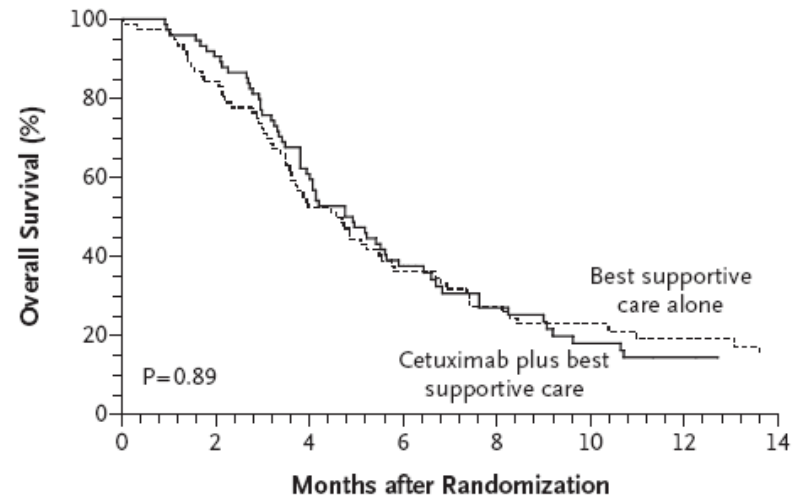
B Wild-type *K-ras*



No. at Risk

Cetuximab plus best supportive care	110	101	88	75	48	31	19
Best supportive care alone	105	88	65	34	23	17	12

A Mutated *K-ras*



No. at Risk

Cetuximab plus best supportive care	75	67	45	26	15	10	7	4
Best supportive care alone	76	64	39	26	19	12	10	7

COSA Tissue Banking workshop

- 1-day workshop 24 October 2008
- Attendance by biobanks, CCTGs, cancer registries, cancer organisations & consumers
- Aims:
 - Explore co-ordinated approach to collection, storage and efficient utilisation of cancer clinical trial specimens
 - Explore appropriate funding mechanisms
- Mix of presentations and small group discussion

Key questions

- Minimum data elements
- Standardised consent/ethics process
- Collection & storage of samples
- Distribution of samples & sustainability
- Funding options
- COSA's role

Minimum data elements

- Demographic identification of trial and specimen
- Data elements for each trial
 - Primary questions, trial contacts, specimen type, consent, potential for collaboration
- Data elements for each specimen
 - Trial ID, patient ID, tumour type, tissue type, collection method, date, storage location, consent

Standardised consent/ethics

- Goal for all patients to consent to sample storage for future research (opt-out approach)
- Need for increased awareness of guidelines & public education
- Questions around consent timing, process etc
- COSA role:
 - Lobbying & liaison with Royal Colleges
 - Review guidelines and develop standardised approaches
 - Public education

Collection and storage

- Possible approaches to improve consistency:
 - Greater inclusion of pathology & pathologists
 - Explore options for reimbursement
 - Pre-define translational research question
 - ‘Virtual’ network (local collection, national access)

COSA’s role:

- Collaboration with RCPA
- Lobbying for Medicare number
- Tendering for activities to support localised collection/storage

Distribution & sustainability

- Aim to quarantine clinical trial samples
- TMC to retain governance
- Tender process to supply tissue collection services
- Open collection samples managed by tissue bank
- Sustainability dependent on:
 - Best practice & SOPs
 - Database management & linkages
 - Funding (COSA to advocate for funding)
 - Consolidation of effort

Funding

- Funding sources:
 - Government/government agencies
 - Trial sponsors/commercial entities
 - Philanthropic donations
 - NGOs
 - Overseas sources
- Questions:
 - Who receives funds?
 - Who 'owns' the specimen?
 - Long-term cost-effectiveness of targeted Rx?

Ways forward

- Build a business case:
 - Scoping of current activity
 - Health economic assessment
 - Identification of potential funding sources
- Joint submission with RCPA to Government re: Medicare item number
- Build on existing NHMRC Enabling Grant
- Ongoing dialogue/collaboration

Workshop report

- www.cosa.org.au/publicationspositionstatements
- kathy.ansell@cancer.org.au

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- Facilitator: Ian Olver
- Funders: Roche Products Pty Ltd (Gold), Novartis Pharmaceuticals Australia (Silver)
- Writer: Alison Evans

Personal view

- Consent
 - standardised consent prior to every cancer operation (opt-out?)
- Trial Design
 - when designing a clinical trial, always have a translational question and aim
- Collection
 - make tissue collection routine clinical practice
 - KISS principle: don't impose complex management routines – they may not be necessary