Symptom Benefit Study

Update and current status

GCIG Symptom Benefit Study

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

PoCoG

ANZGOG
www.anzgog.org.au

GRANT Success !

Dear Professor Friedlander,

NHMRC Grant Application: APP1063012
Application Round: 2013 Project Grant Funding Commencing 2014

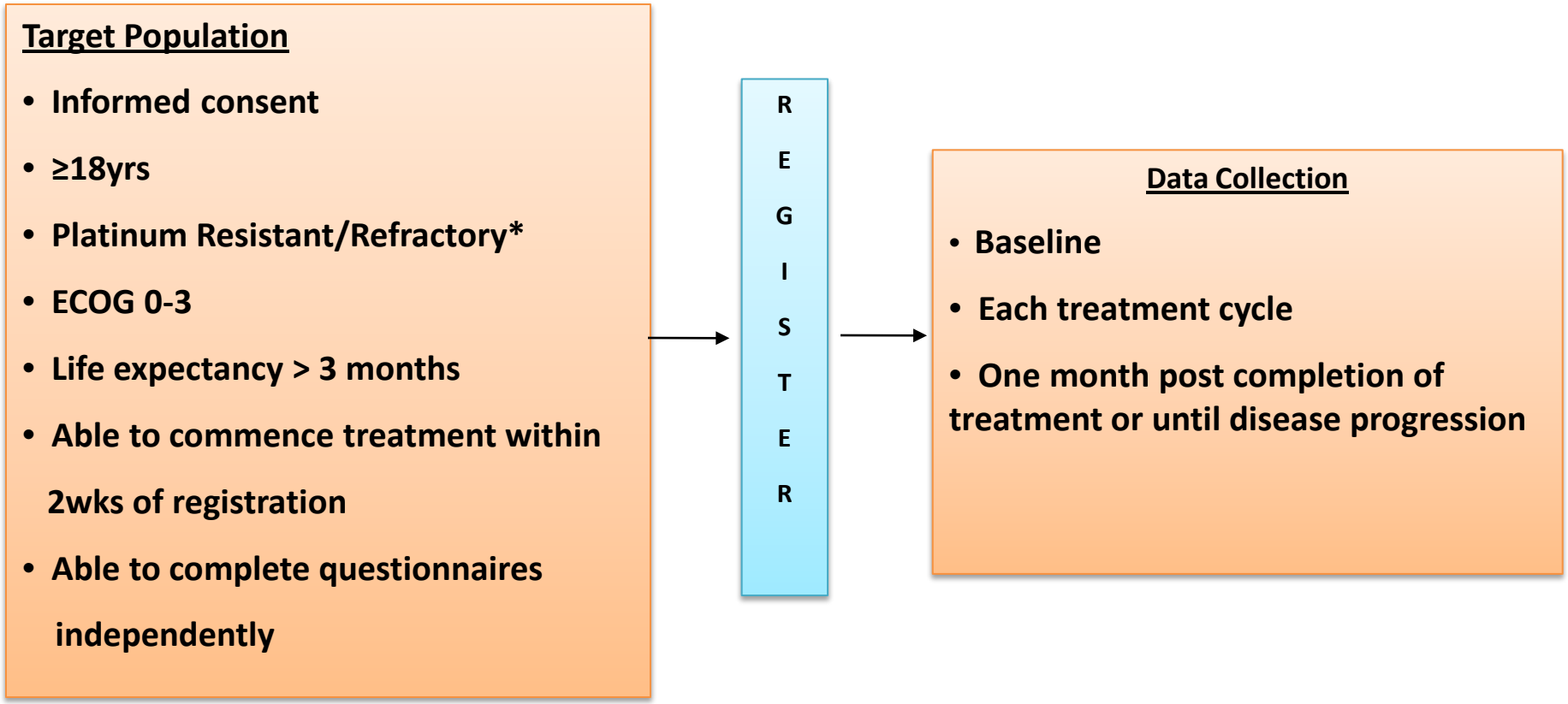
Title: Symptom Benefit: Does palliative chemotherapy palliate?

Outcome: **Successful**
Budget: The approved budget for this Grant is $394,744.50. Duration: 2 years. I am pleased to advise that your application has been approved.

Yours sincerely,

Dr Tony Willis
Acting Executive Director
Research Programs
National Health & Medical Research Council

Schema – Stage 2-SBS



* Amendment included ALL patients receiving 3rd line or greater lines of treatment - including potentially platinum sensitive

Stage 2 -SBS

Primary aim is to validate the MOST as an outcome measure for future clinical trials

Secondary aims

- To evaluate criteria for clinically significant subjective improvement
- The proportion of women benefiting from palliative chemotherapy
- The time to symptom deterioration
- The proportion of women who receive treatment because they are (a) symptomatic, (b) have rising tumor markers alone, or (c) have imaging evidence of disease progression
- The percentage of patients who complete 4 or more cycles of treatment
- The most common, most severe and most noticed symptoms as perceived by patients.
- **Develop a prognostic index**

Data Collection

Baseline data collection

1. Reason for treatment (symptomatic, rising CA125 and or radiological evidence of progression)

2. Number of lines of previous chemotherapy

3. Classification as primary or secondary platinum-resistant or –refractory

4. Baseline tumour assessments (CA 125 and imaging)

5. Symptoms and toxicities present at baseline

6. Patient-reported symptoms and HRQOL assessments

7. Prognostic factors - include performance status, age, haemoglobin, white cell count and differential, platelet count, CRP, albumin, CA125 doubling time prior to study entry and number of metastatic sites.

Data collected 3-4 weekly during and after chemotherapy until progression

1. Symptom and HRQOL assessments, completed 3-4 weeks after each treatment cycle

2. Chemotherapy details

3. Adverse events and performance status

4. Tumour response assessment with CA 125 and imaging as clinically indicated

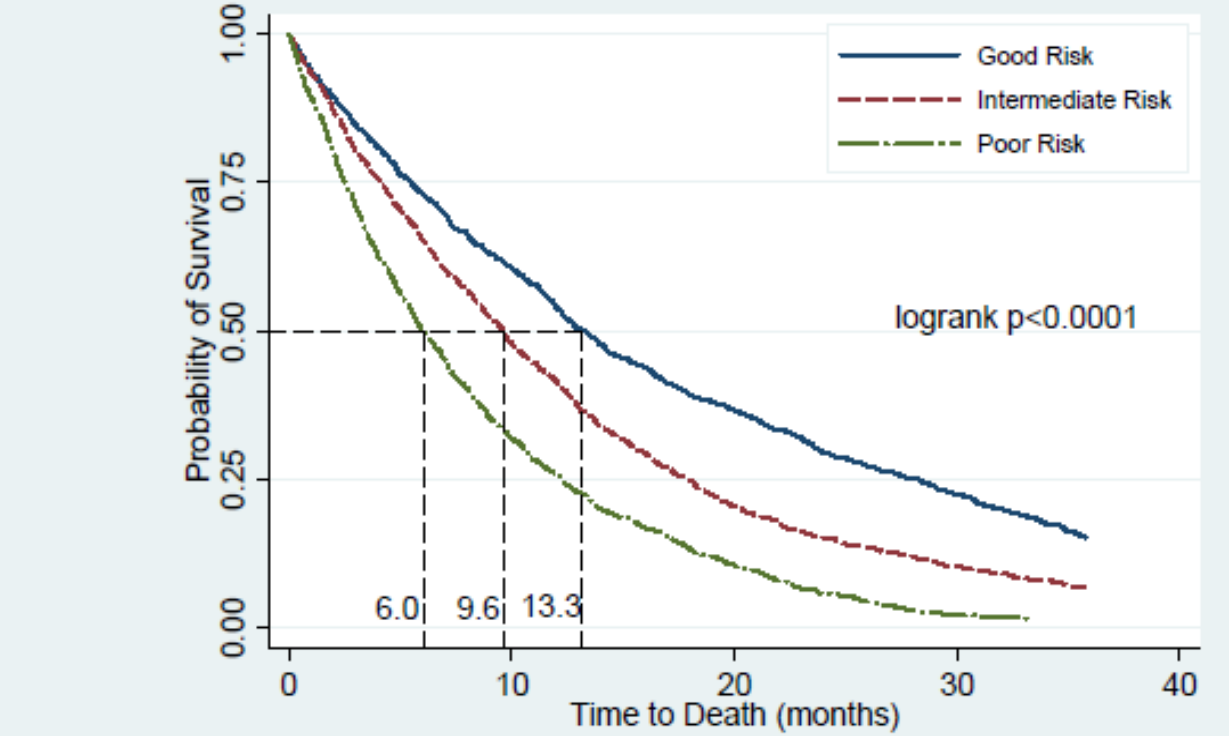
Prognostic Factors

Traditional Factors	Potential Additional Factors
Performance status	HRQOL (FOSI +/- ECOG status)
Response to prior therapy	Symptoms (large volume ascites, abdominal cramping)
Refractory vs. resistant	weight loss
CA125 only vs. measurable disease	BRCA mutation or family history of breast cancer
Volume of tumour	Measures of inflammation (CRP, Haemoglobin, WCC, platelets, LDH, alkaline phosphatase)
Number of metastatic sites	CA125 velocity
Histology Serous vs. Clear Cell vs. Mucinous	
Grade	

Platinum Resistant Ovarian Cancer

Hypothetical Risk Groups

OS



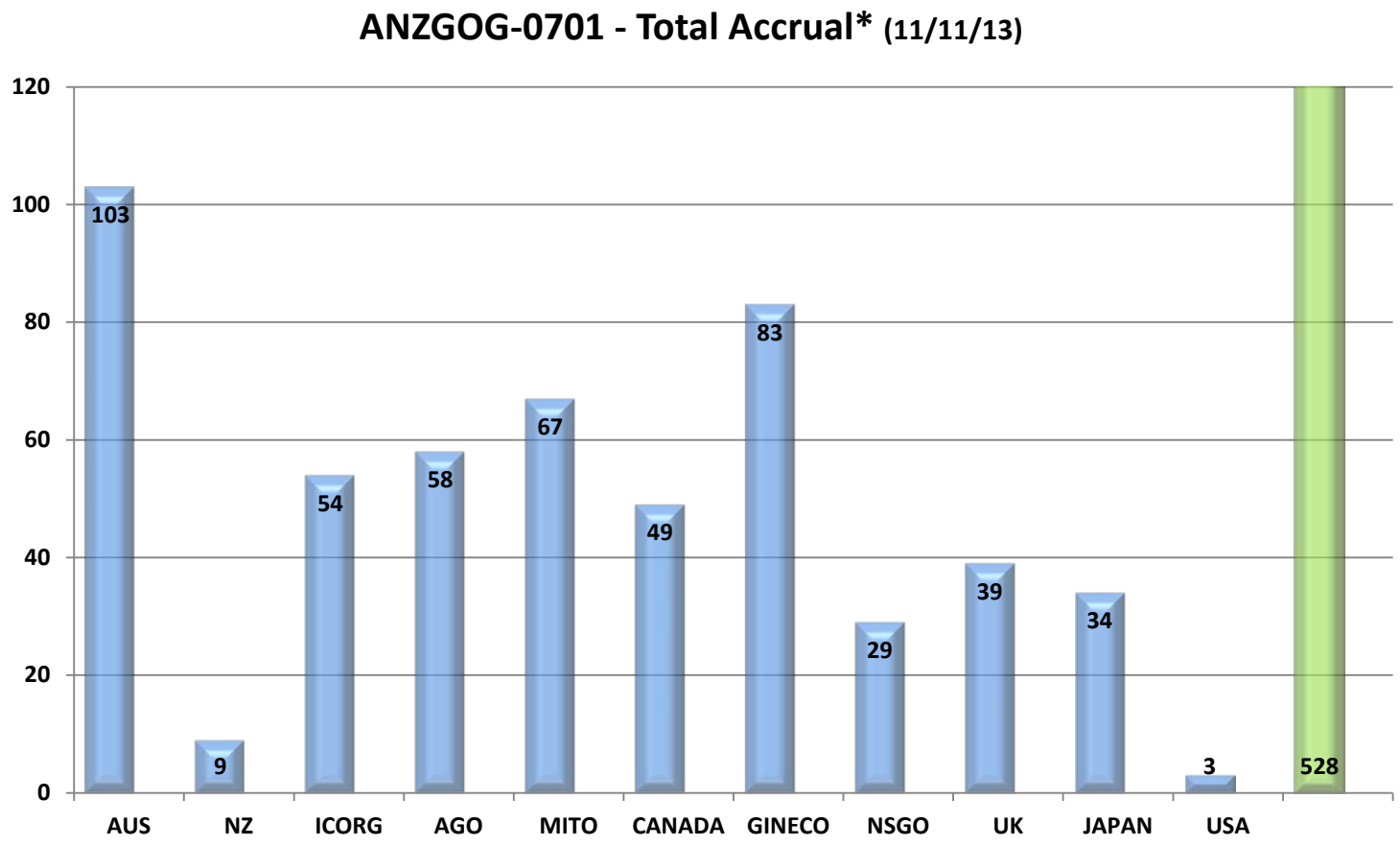
Expected Outcomes

1) A validated instrument to precisely measure the subjective benefit of palliative chemotherapy (the MOST-OSI)

2) Prognostic model to better predict likelihood of symptomatic benefit, time to progression and overall survival.

3)Patterns of care and outcomes in women with platinum resistant/recurrent ovarian cancer who are not entered on clinical trials- will provide information regarding outcomes in a ‘clinic population’.

Total Accrual



*1st patient: Feb 2011

Projected Accrual

- Currently averaging 32 registrations per month
- At current rate, total projected accrual would be 963 at study close (31 Dec 2014)
- Sample size: 600 patients with *evaluable* data (Cycle 3)
- On target for study timelines

Current Progress

- Writing a User Guide- essential to guide scoring and appropriate use of the Instrument.
- SAP in place
- Commencing analyses in the 1st 400 patients and will use the next 400 as the validation set
- 3 papers from Stage 1 - 1 published (The Oncologist),1 accepted(IJGC) pending changes suggested by reviewers and 1 submitted(IJGC) and waiting on reviewers comments

Discussion Points

- Suggest that the instrument is called the GCIG-MOST providing that there is agreement by GCIG
- The instrument would be made freely available to whoever wishes to use it in clinical trials.
- The MOST instrument and User Manual will be available on GCIG website as well as ANZGOG and PoCOG websites