



AUSTRALIA NEW ZEALAND
GYNAECOLOGICAL ONCOLOGY GROUP

OUTBACK

(ANZGOG 0902 / GOG 0274 / RTOG 1174)

A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone

Principal Investigator: A/Prof Linda Mileskin

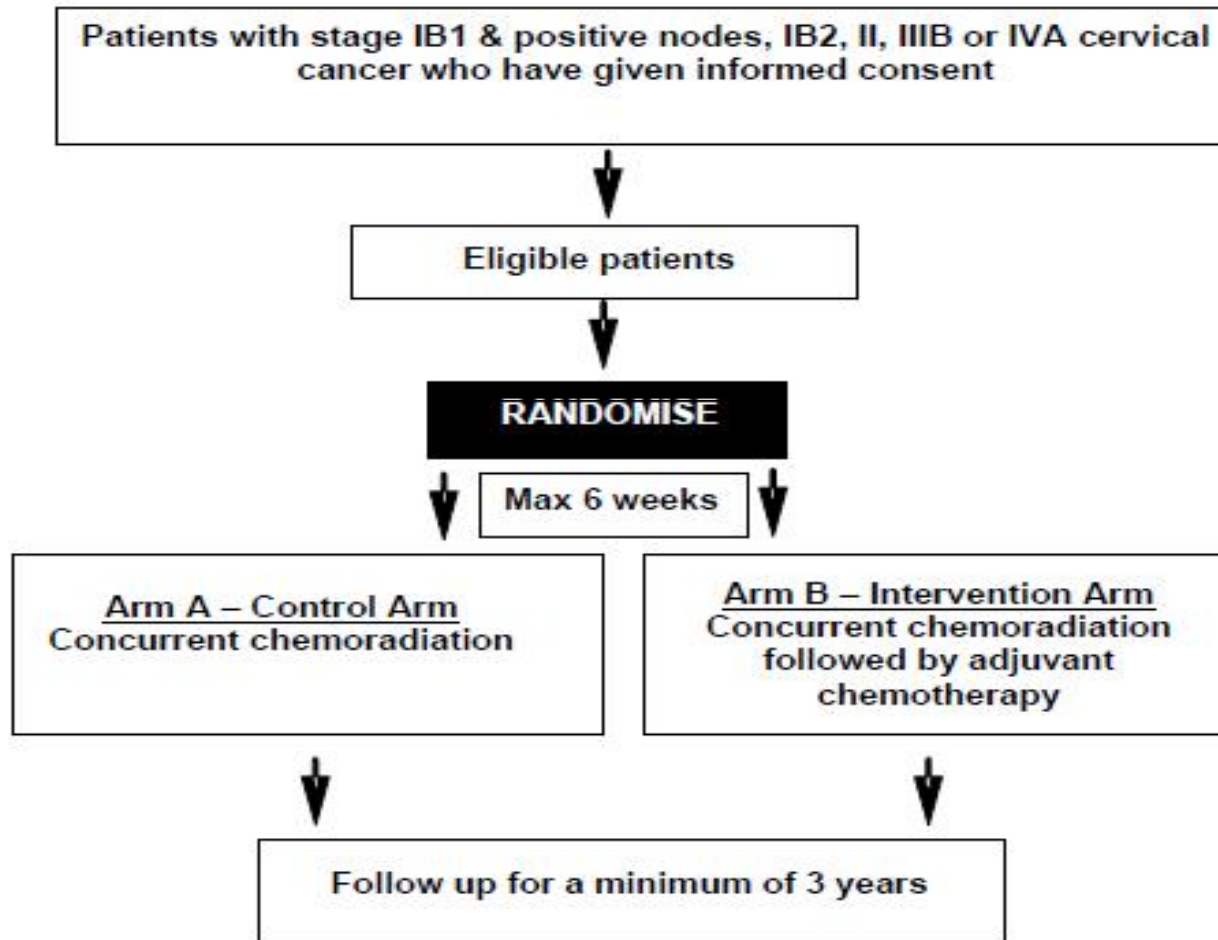


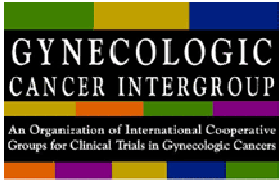
The University of Sydney



NHMRC
Clinical Trials Centre

Study Schema





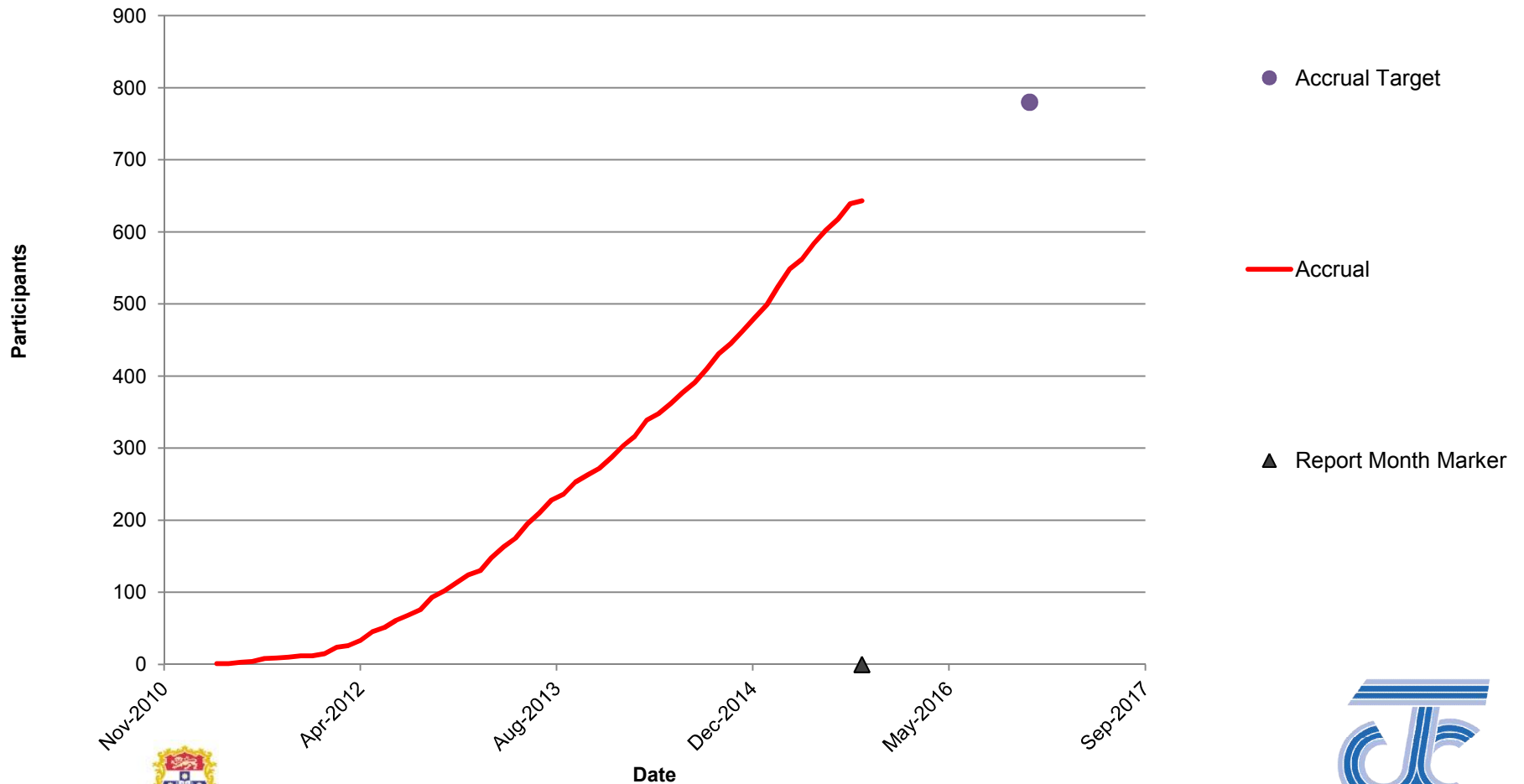
Trial Status

- 260 sites open (15 ANZGOG, 245 NRG Oncology)
- Sites in Australia, New Zealand, USA, Canada, Saudi Arabia & Singapore
- Trial to possibly open in China, Columbia & Brazil
- 643 patients recruited (129 ANZGOG, 514 NRG Oncology)
- Accrual target is 780 patients



Accrual Graph

Accrual



Serious Adverse Events

- 261 SAEs have been reported
 - No SUSARS

| Treatment Phase | SAEs | Related | Unrelated |
|-----------------------|------|---------|-----------|
| Chemoradiation | 203 | 124 | 79 |
| Adjuvant chemotherapy | 58 | 29 | 29 |

- Event rate too low to perform initial futility analysis yet
- Ongoing efforts to improve submission of cases for radiotherapy QA

