ANZ GOG AUSTRALIA NEW ZEALAND GYNAECOLOGICAL ONCOLOGY GROUP

OUTBACK

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

Study Chair: A/Prof Linda Mileshkin

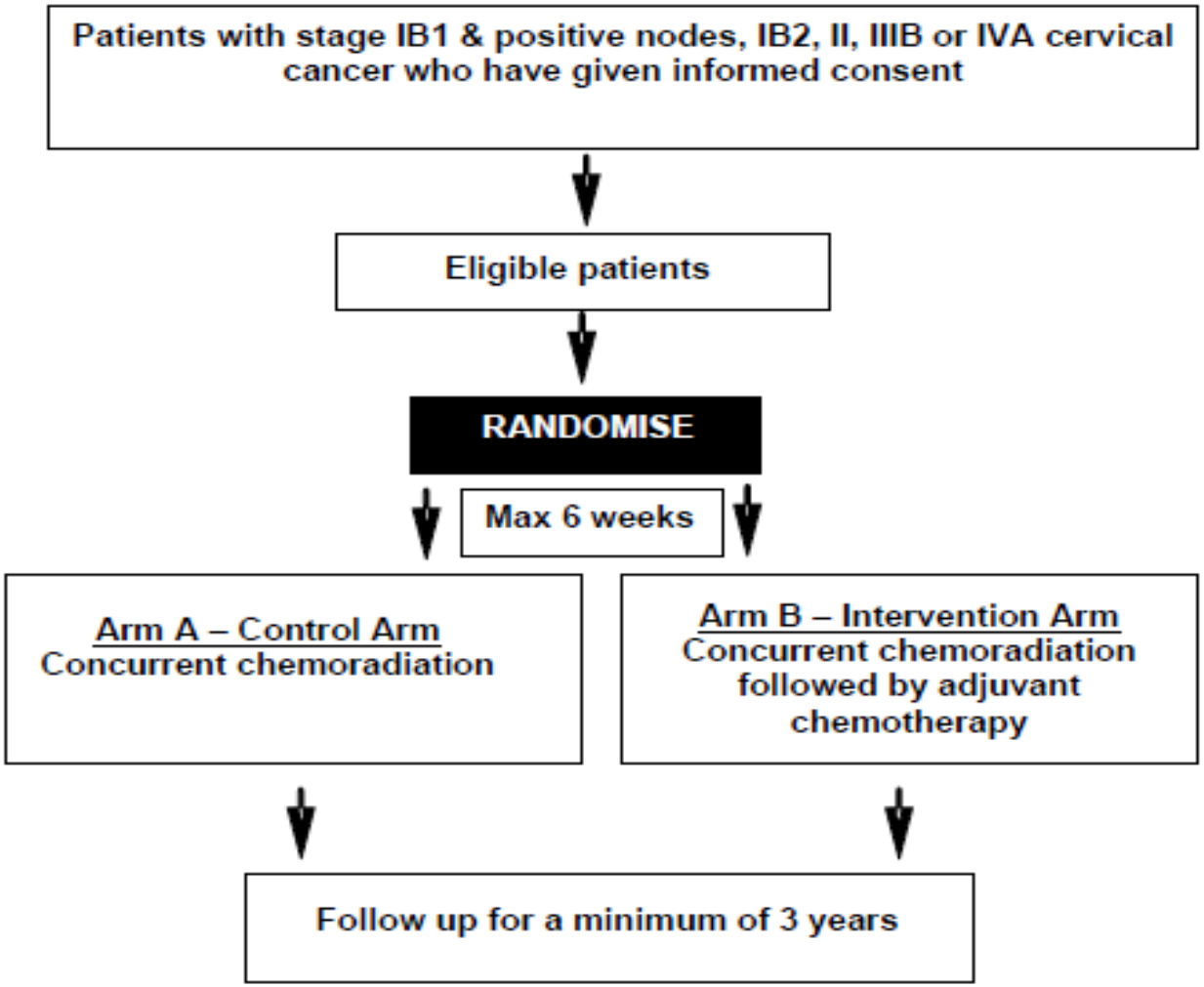
NRG ONCOLOGY

Advancing Research. Improving Lives.™

GYNECOLOGIC CANCER INTERGROUP

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

Schema


Patients with stage IB1 & positive nodes, IB2, II, IIIB or IVA cervical cancer who have given informed consent
Eligible patients
RANDOMISE
Max 6 weeks
Arm A – Control Arm
Concurrent chemoradiation
Arm B – Intervention Arm
Concurrent chemoradiation followed by adjuvant chemotherapy
Follow up for a minimum of 3 years

Objectives

Primary objective: To determine if adding adjuvant chemo to standard chemoXRT improves overall survival

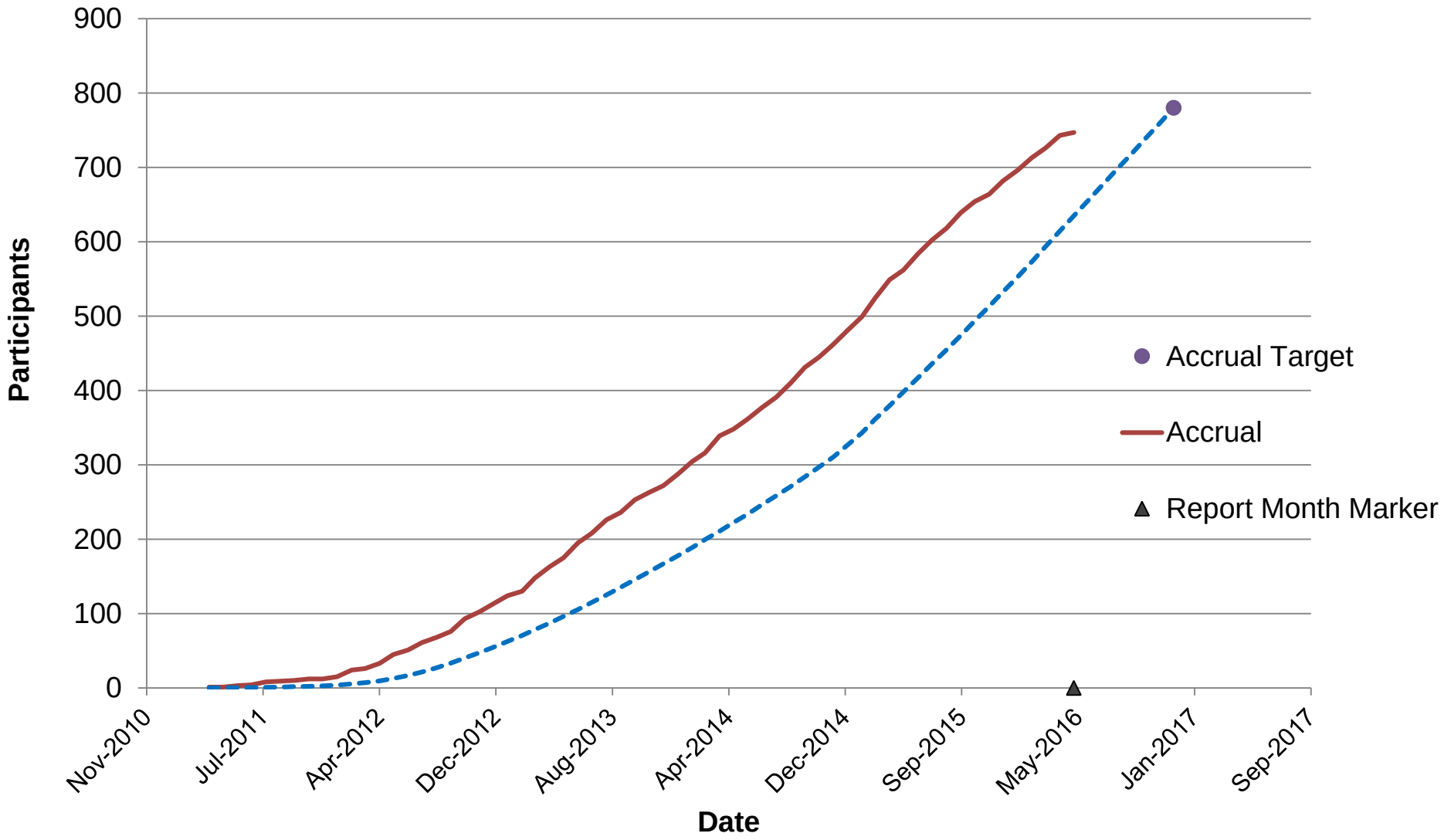
Secondary objectives: To determine;

- Progression-free survival rates
- Acute and long-term toxicities
- Patterns of disease recurrence
- The association between RT compliance and outcomes
- Patient QOL, including psycho-sexual health

Tertiary objectives:

- To collect blood and tissue for future translational studies
- To explore the association between complete metabolic response on post-treatment PET and outcomes

Accrual Chart



Current status

	ANZGOG		NRG				
Country	**Australia**	**New Zealand**	**USA**	**Canada**	**China**	**Saudi Arabia**	**Singapore**
Sites Open	12	3	256	5	1	1	1
Accrual	125	17	575	22	2	5	1

SAEs

304 SAEs reported

Treatment Phase	SAEs	Unrelated	Related/Expected
Chemoradiation	239	91	147
Adjuvant chemotherapy	65	29	36

- Vast majority have occurred during standard treatment (XRT) most of which were expected
- No SUSARS

Radiotherapy QA

160 QA reports finalised

- 44 major deviations
- 89 minor deviations
- 17 patients had multiple deviations

Next steps

- IDSMC recently approved proposal to increase sample size from 780 to 900
- Protocol amendment submitted to regulatory authorities for ANZ and NRG
- Continue recruitment and follow-up
- Continue RT QA