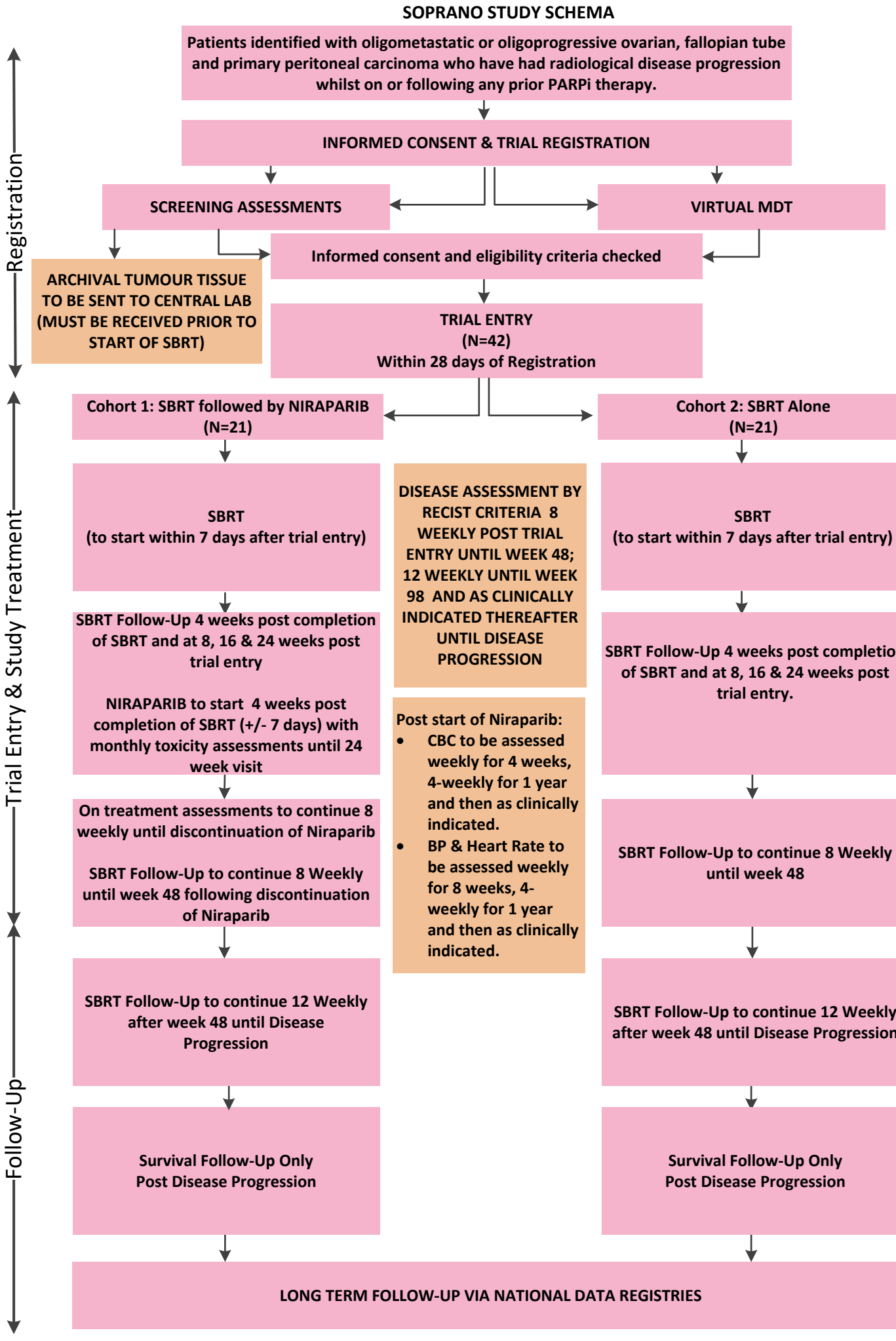
SOPRANO STUDY SCHEMA
Patients identified with oligometastatic or oligoprogressive ovarian, fallopian tube and primary peritoneal carcinoma who have had radiological disease progression whilst on or following any prior PARPi therapy.
INFORMED CONSENT & TRIAL REGISTRATION
SCREENING ASSESSMENTS
VIRTUAL MDT
Informed consent and eligibility criteria checked
ARCHIVAL TUMOUR TISSUE TO BE SENT TO CENTRAL LAB (MUST BE RECEIVED PRIOR TO START OF SBRT)
TRIAL ENTRY (N=42) Within 28 days of Registration
Registration
Cohort 1: SBRT followed by NIRAPARIB (N=21)
Cohort 2: SBRT Alone (N=21)
SBRT (to start within 7 days after trial entry)
SBRT (to start within 7 days after trial entry)
DISEASE ASSESSMENT BY RECIST CRITERIA 8 WEEKLY POST TRIAL ENTRY UNTIL WEEK 48; 12 WEEKLY UNTIL WEEK 98 AND AS CLINICALLY INDICATED THEREAFTER UNTIL DISEASE PROGRESSION
SBRT Follow-Up 4 weeks post completion of SBRT and at 8, 16 & 24 weeks post trial entry
NIRAPARIB to start 4 weeks post completion of SBRT (+/- 7 days) with monthly toxicity assessments until 24 week visit
Post start of Niraparib:
• CBC to be assessed weekly for 4 weeks, 4-weekly for 1 year and then as clinically indicated.
• BP & Heart Rate to be assessed weekly for 8 weeks, 4-weekly for 1 year and then as clinically indicated.
SBRT Follow-Up 4 weeks post completion of SBRT and at 8, 16 & 24 weeks post trial entry.
On treatment assessments to continue 8 weekly until discontinuation of Niraparib
SBRT Follow-Up to continue 8 Weekly until week 48 following discontinuation of Niraparib
SBRT Follow-Up to continue 8 Weekly until week 48
Trial Entry & Study Treatment
SBRT Follow-Up to continue 12 Weekly after week 48 until Disease Progression
SBRT Follow-Up to continue 12 Weekly after week 48 until Disease Progression
Survival Follow-Up Only Post Disease Progression
Survival Follow-Up Only Post Disease Progression
Follow-Up
LONG TERM FOLLOW-UP VIA NATIONAL DATA REGISTRIES