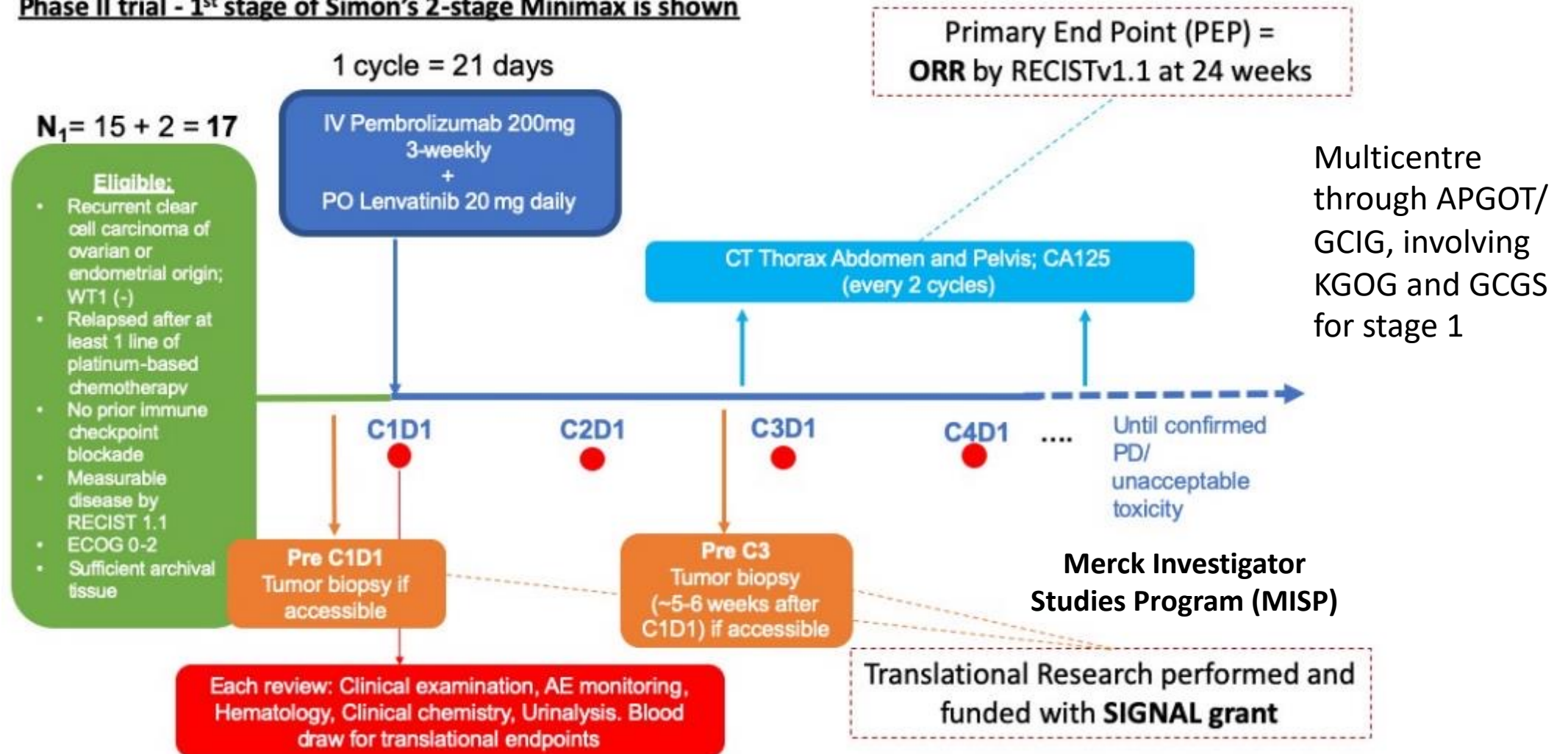


LARA – APGOT OV3

New Study Proposal: A Multicentre Phase II trial of Lenvatinib plus PembrolizumAb in Recurrent gynaecological clear cell Adenocarcinomas (LARA) David SP Tan, Byoung-Gie Kim, Jung-Yun Lee

Phase II trial - 1st stage of Simon's 2-stage Minimax is shown



Multicentre
through APGOT/
GCIG, involving
KGOG and GCGS
for stage 1

New Study Proposal:
A Multicentre Phase II trial of
Lenvatinib plus PembrolizumAb in Recurrent
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LARA Statistical Plan:

- Simon's optimal two-stage minimax design
- Null hypothesis - ORR of 10%, Alternate hypothesis - ORR of 30%.
- 10% significance level (one-sided alpha) and 80% power of rejecting the null hypothesis, 25 patients are required. Allowing for 10% drop out, 28 patients are required for the study.

