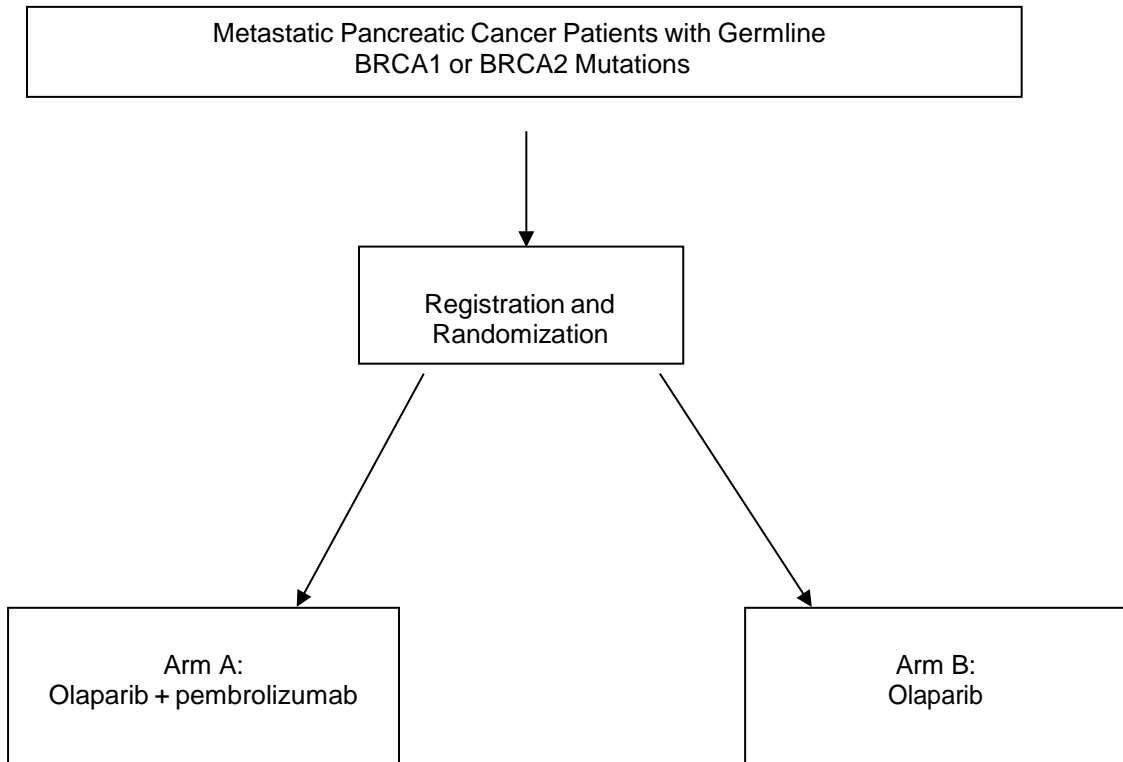


### SCHEMA



## 5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration in OPEN. Section 5 may be printed and used to by the site, but is not to be uploaded in RAVE (unless specially stated). For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave® (see [Section 14.0](#)). Any potential eligibility issues should be addressed to the SWOG SDMC in Seattle at 206/652-2267 or [GIquestion@crab.org](mailto:GIquestion@crab.org) prior to registration. NCI policy does not allow for waiver of any eligibility criterion ([http://ctep.cancer.gov/protocolDevelopment/policies\\_deviations.htm](http://ctep.cancer.gov/protocolDevelopment/policies_deviations.htm)).

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 28 falls on a weekend or holiday, the limit may be extended to the next working day.**

## 5.1 Disease Related Criteria

- a. Patient must have a histologic or cytologic diagnosis of pancreatic adenocarcinoma. Patients with neuroendocrine tumors, acinar cell and adenosquamous carcinomas are excluded. All disease must be assessed and documented on the Baseline Tumor Assessment Form.
- b. Patients must have one of the following mutations: germline mutation in BRCA 1 or 2 that was tested in a CLIA certified lab defined as positive and/or deleterious (that is, pathogenic or likely pathogenic variant). (NOTE: Patients with tumor somatic mutations are not eligible). The Germline Testing Report must be submitted per [Section 14.4a](#).
- c. Patient must have metastatic disease and received first line platinum-based chemotherapy (i.e. FOLFIRINOX, FOLFOX, or gemcitabine + cisplatin)
- d. Patients must have had a CT or MRI showing stable or responding disease on first line platinum-based chemotherapy within 30 days prior to registration.
- e. Patients with known human immunodeficiency virus (HIV)-infection are eligible providing they are on effective anti-retroviral therapy and have undetectable viral load at their most recent viral load test and within 6 months prior to registration.
- f. Patients with history of chronic hepatitis B virus (HBV) infection must have undetectable HBV viral load within 30 days prior to registration.
- g. Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment must have an undetectable HCV viral load within 30 days prior to registration.

## 5.2 Prior/Concurrent Therapy Criteria

- a. Patients must have received at least 16 weeks but no more than 24 weeks of first line platinum-based therapy for metastatic disease.
- b. Patients' last chemotherapy treatment must be within 30 days prior to registration.
- c. Patients must have resolved or stable  $\leq$  Grade 1 toxicity from prior administration of another investigational drug and/or prior anti-cancer treatment, excluding neuropathy and alopecia
- d. Patients must not have a known hypersensitivity to olaparib or any of the excipients of the product.
- e. Patients must not be planning to receive strong or moderate CYP3A inhibitors or inducers (See [Section 3.2c.3](#)) while on olaparib treatment. Patients receiving strong or moderate CYP3A inhibitors must discontinue use at least 2 weeks prior to receiving olaparib. Patients receiving strong or moderate CYP3A inducers must discontinue use at least 5 weeks prior to receiving olaparib. Medications should be checked using a **frequently updated medical reference** for a **list of drugs to avoid**.
- f. Patients must not have received live vaccines within 42 days prior to randomization and must not be planning to receive live virus or live bacterial vaccines while receiving study treatment and during the 30 day follow up period. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, chicken pox, shingles, yellow fever, rabies, BCG, and typhoid (oral) vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and

are allowed; however, intranasal influenza vaccines (e.g., Flu-Mist®) are live attenuated vaccines, and are not allowed.

- g. Patients must not have had prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent, or any other immune checkpoint inhibitors.
- h. Patients must not have had prior therapy with PARP inhibitors.
- i. Patients must not have had a prior diagnosis of immunodeficiency or receiving systemic steroid therapy (defined as  $\geq 10$  mg prednisone or equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of trial treatment.

### 5.3 Clinical/Laboratory Criteria

- a. Zubrod performance status of 0-1.
- b. Patients must be  $\geq 18$  years old.
- c. Patients must have a complete medical history and physical exam within 28 days prior to registration.
- d. Patients must have adequate organ and marrow function within 14 days of registration, as defined below:
  - absolute neutrophil count  $\geq 1,500/\text{mcl}$
  - platelets  $\geq 100,000/\text{mcl}$
  - total bilirubin  $\leq 1.5$  institutional upper limit of normal (ULN)
  - AST/ALT  $\leq 3 \times$  institutional ULN
  - creatinine  $\leq 1.5$  mg/dl
  - Albumin  $\geq 3.0$
  - Hemoglobin  $\geq 9.0$  g/dL
- e. Patients must have CA19-9 obtained within 42 days prior to registration.
- f. Patients must be able to swallow and retain oral medications and have no known gastrointestinal disorders likely to interfere with absorption of the study medication.
- g. Participants with a prior or concurrent malignancy whose natural history or treatment (in the opinion of the treating physician) does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial provided it does not require concurrent therapy.
- h. Participants must not be pregnant or nursing due to the possibility of harm to the fetus or nursing infant from this treatment regimen. Women/men of reproductive potential must have agreed to use an effective contraceptive method for the course of the study through 6 months after the last dose of study medication. A woman is considered to be of "reproductive potential" if she has had menses at any time in the preceding 12 consecutive months. In addition to routine contraceptive methods, "effective contraception" also includes heterosexual celibacy and surgery intended to prevent pregnancy (or with a side-effect of pregnancy prevention) defined as a hysterectomy, bilateral oophorectomy or bilateral tubal ligation. However, if at any point a previously celibate participant chooses to become heterosexually active during the time period for use of contraceptive measures outlined in the protocol, he/she is responsible for beginning contraceptive measures. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately.

- i. Patients must not have a history of (non-infectious) pneumonitis that required steroids or current pneumonitis.
- j. Patients must not have an active infection requiring systemic therapy.
- k. Patients must not have active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment.

#### 5.4 Specimen Submission Criteria

- a. Patients must be offered the opportunity to participate in specimen banking of FFPE tissue and whole blood as outlined in [Section 15.1](#). If a patient is unable to submit archival tissue, should the patient need to undergo a standard of care biopsy per NCCN guidelines, patients must then be offered the opportunity to submit the fresh tumor tissue from that biopsy. With participant consent, specimens must be collected and submitted via the SWOG Specimen Tracking System as outlined in [Section 15.1](#).

#### 5.5 Regulatory Criteria

- a. Patients **must** be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines. For participants with impaired decision making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and CIRB regulations.
- b. As a part of the OPEN registration process (see [Section 13.5](#) for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.