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| Big Ten Cancer Research Consortium Letter of Intent | |
| Study Title |  |
| Study Phase |  |
| LOI Submission Date |  |

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| SPONSOR-INVESTIGATOR | |
| **Name** |  |
| **Lead Institution** |  |
| **Address** |  |
| **Phone** |  |
| **Fax** |  |
| **Email** |  |
| COLLABORATING INVESTIGATOR | |
| **Name** |  |
| **Institution** |  |
| **Phone** |  |
| **Email** |  |

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| STUDY DRUG(S) AND FUNDING SOURCE | |
| **Name of Study Drug(s)** |  |
| **Study Drug Supplier** |  |
| **Placebo?** | Yes  No |
| **Name of Commercial Drug(s)** |  |
| **Trial Funding Source(s)** |  |
| **MSL contact** |  |

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| STUDY DESIGN INFORMATION | |
| **Background and Rationale** |  |
| **Hypothesis** |  |
| **Objectives**  Primary |  |
| Secondary |  |
| **Endpoints**  Primary |  |
| Secondary |  |
| **Indication** |  |
| **Study population** |  |
| **Diversity and inclusion**  *How will your proposal support diversity in enrollment access and inclusion of people of varying age, race, ethnicity, and gender?* |  |
| **Key inclusion/exclusion criteria** |  |
| **Treatment Plan**  *State the dose, method of administration, and schedule of each drug, and, if phase 1, provide the dose escalation scheme, and definitions of DLTs.* |  |
| **Study Assessments**  *Specify all non-routine care assessments and their specific time points using objective practice guidelines (e.g., NCCN).* |  |
| **Follow-up durations** |  |
| **Estimated Accrual (per month)** |  |
| **Estimated Total Study Duration** |  |
| **Statistical Methods  (include sample size justification and stopping rules)** | Sample size justification:  Stopping rules: |
| **Publication Plan**  *List specific journals, scientific meetings, and target dates for publication and presentation.* |  |
| **Does this proposal involve an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application?** *(Please choose one)* | IND  IDE |
| **Additional Comments  (e.g., rare population, significant challenges, contingencies)** |  |

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| CORRELATIVE STUDIES (PHARMCOKINETICS / PHARMACOGENOMICS) | |
| **Describe proposed correlative studies. Please specify which sample collections are optional vs. mandatory for study participation.** |  |
| **Funding source for correlative studies** |  |

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| REFERENCES |
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| ACKNOWLEDGEMENT |
| **By submitting this LOI, the sponsor-investigator acknowledges:**     * Big Ten CRC studies are early-phase (phase II and earlier) investigator-initiated studies sponsored by member institutions with a strong likelihood of successful accrual within the Big Ten CRC. The Big Ten CRC Steering Committee may approve exceptions to permit the Big Ten CRC to conduct investigator-initiated Phase III studies with a strong likelihood of successfully accruing within the Big Ten CRC given the accrual goals, the number of Big Ten CRC sites committed to participating in the studies, those sites’ feasibility assessments, and the compatibility of the studies with the research strengths of the Big Ten CRC. The Big Ten CRC will not conduct industry-sponsored studies. * Sponsor-investigators of Big Ten CRC studies must be employed by Big Ten CRC member institutions. * Sponsorship of Big Ten CRC studies may not transfer to a non-member institution. * Big Ten CRC studies are conducted at Big Ten CRC member institutions. Outside institutions may not participate in Big Ten CRC studies without approval by the Steering Committee, and only after all member institutions have been offered the opportunity to participate.   **Big Ten CRC Research Criteria:** <https://www.bigtencrc.org/clinical-research/research-criteria/> |