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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** |  |
| OTHER CONTACTS |
| **Name** |  |
| **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 |
| **Synopsis** |  |
| **Rationale** |  |
| **Hypothesis** |  |
| **Objectives**Primary |  |
| Secondary |  |
| **Endpoints**Primary |  |
| Secondary |  |
| **Indication** |  |
| **Study population** |  |
| **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** |  |
| **Sample Size and justification** |  |
| **Estimated Accrual (per month)** |  |
| **Estimated Total Study Duration** |  |
| **Statistical Methods (include stopping rules)** |  |
| **Publication Plan** |  |
| **Do you plan to submit an Investigational New Drug (IND) application or Investigational Device Exemption (IDE)?** | [ ]  Yes [ *specify* ][ ]  No  |
| **Additional Comments (e.g., 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.
* 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/> |