**SNAP Trial: Sub-study Expression of Interest (EOI)**

An Expression of Interest (EOI) is the first stage of the review process for all sub studies. The sub-study lead(s) will be required to complete the sub-study EOI template and return the completed form to the SNAP Management Team ([snap-trial@unimelb.edu.au](mailto:snap-trial@unimelb.edu.au)).

Please refer to the [**SNAP Trial Sub-Study Guidance Document**](https://www.snaptrial.com.au/for-investigators#integrity) for more information.

The EOI will be reviewed by the Design Working Group and their recommendation noted at the next GTSC meeting. All comments/questions will be returned to the sub-study lead(s) within two weeks of the Design Working Group review.

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| 1. **SUBSTUDY INVESTIGATOR DETAILS** | |
| Name of Project Leader *(lead person)* |  |
| Email Address |  |
| Institution & Region |  |
| Other Sub-Study Collaborators |  |
| Do you or any sub-study collaborators have any conflicts of interest to declare? | Yes  No |
| If yes, please state details of the perceived conflict(s) |  |

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| 1. **SUBSTUDY PROJECT DETAILS** | |
| Title of project: |  |
| Proposed Short Title of Project *(if available)*: |  |
| Proposed Sub-Study Category  (*See Substudy SOP for further detail)* | New domain  Integrated/Nested Clinical Trial  Prospective Sub-Study  Secondary Use of Data & Biospecimens Analysis |
| Proposed Regions | Any regions interested in participating  Specific Regions *(please specify):* |
| SNAP Enrolment  *(select one)* | Platform Patients Only  Registry Patients Only  Both Platform AND Registry Patients  Divert Patients from SNAP |
| SNAP Participants  *(select all that apply)* | Adults  Children  Pregnant Patients  Other *(please specify):* |
| Timeline and Deadlines/Milestones for the project:  *(Include recruiting start and data collection finish dates. If there is a grant associated, please provide details regarding the key milestones)* |  |

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| 1. **SUBSTUDY PROPOSAL OUTLINE – *No more than 700 words*** | |
| Background and Rationale |  |
| Hypothesis/Research Questions |  |
| Methods |  |
| Project Endpoints/Outcomes |  |
| What data points and/or specimens are required or brief schedule of events |  |

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| 1. **SUBSTUDY REVIEW CRITERIA – *Please provide a brief justification/response to each of the following points. Where a section is not relevant to the project, please indicate ‘Not applicable’ in your response.*** | |
| **Trial Integrity**  *Does this sub-study require access to data that could threaten trial integrity? Does this sub-study wish to report on trial outcomes prior to the SNAP Trial Results paper? Does the sub-study wish to report on sub-study outcomes by treatment allocation prior to the SNAP Trial Results paper?* |  |
| **Harmony with SNAP Protocol**  *Are the sample/data collection harmonised with the SNAP core protocol and other SNAP sub-studies?* |  |
| **Adoption of the Pragmatic Trial Approach**  *Does this sub-study place a significant additional burden on the participant or the site study team? Does the proposal include only the necessary data collection to answer the research question?* |  |
| **Feasibility**  *Is the sample size reasonable and achievable? Will the research question be able to be answered recruiting only SNAP Trial participants?* |  |
| **Global Application**  *Has the investigator considered the ability for the sub-study to be conducted in other regions/countries? Is the protocol applicable to other countries/regions?* |  |
| **Paediatric & Pregnancy Involvement**  *Has the investigator considered the involvement of children and pregnant patients? If not involving these participants, has this been sufficiently justified?* |  |
| **Funding**  *Has funding for this sub study been considered or obtained? Are there any grants the investigator is intending to apply for to cover the costs of the sub-study? Has a proposal been put forward to the central team for covering some or all of the costs?* |  |
| **Sample Collection, Analysis & Shipping**  *Will samples be collected for this sub study and shipped to an external location? Has the shipping and storage of theses samples been considered? Has a plan for the analysis been generated?* |  |
| **Integration with the Statistical Model**  *Will this sub-study require integration into the overall SNAP statistical model?* |  |

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| 1. **Design WG REVIEW – *TMG USE ONLY*** | |
| Date of Design WG Review: |  |
| Decision: | Revise EOI & Respond to Comments *(Section 6 below)*  Proceed to Full Protocol & Respond to Comments, if required *(Section 6 below)*  Recommend for ratification by TSC and proceed to Data / Isolate Request Process  Recommend not proceed further at this time  Recommend for co-enrolment |

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| 1. **RESPONSE TO QUERIES *– Please complete this section upon resubmission of your EOI if required*** | |
| Query 1: | Query 1 Response: |
| Query 2 (repeat as required): | Query 2 Response (repeat as required): |

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| 1. **GTSC RATIFICATION – *TMG USE ONLY*** | |
| Date of GTSC Meeting: |  |
| Document Ratified | EOI & Proceed to Data/Isolate Request *(Secondary Use of Data Only)*  Full Protocol *(all other sub-studies)* |