

Investigator Initiated Clinical Trial Milestones – For Funding Periods

	Milestone	Performance Indicator	Date
<i>Insert Year (pre-funding period)</i>			
<input type="checkbox"/>	Protocol Development	Finalise protocol	
<i>Insert Year (pre-funding period)</i>			
<input type="checkbox"/>	Protocol development	Protocol approved by Scientific and Consumer Review	
<input type="checkbox"/>	Key personnel	Researchers, Statistics, Health Economics, QoL, Consumers, Trial Coordinator/Nurse, Data Manager	
<input type="checkbox"/>	Research Staff	Allocation of staff % FTE, Good Clinical Practice training and appropriate qualifications	
<input type="checkbox"/>	Funding Body - Budget	Budget review	
<input type="checkbox"/>	Patient Informed Consent Sheet Developed	PICF reviewed and approved by Scientific and Consumer Committee	
<input type="checkbox"/>	Site selection	Sites invited to participate in trial – Choose Lead Site	
<input type="checkbox"/>	Contracts and Indemnities	Contracts and Indemnities sent to participating sites (including schedule 2 – Site Budget)	
<input type="checkbox"/>	Standard Operating Procedures	Standardised processes	
<input type="checkbox"/>	Recruitment	Recruitment strategy/plan	
<input type="checkbox"/>	Trial registered	Trial entered on ANZCTR	
<input type="checkbox"/>	HREC submission – Lead -Site (for Multi-Centre)	Application submitted	
<input type="checkbox"/>	HREC approval	Notification received of approval	
<input type="checkbox"/>	Site Specific Applications	Applications submitted	
<input type="checkbox"/>	Research Governance Submissions	Documents submitted for review	
<input type="checkbox"/>	Research Governance Approvals	Notification received of approval	
<input type="checkbox"/>	TGA CTN Application (if required)	CTN Submission	
<input type="checkbox"/>	TGA CTN Approvals (if required)	Site Approvals	

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<input type="checkbox"/>	eCRFs and Database created	Database reviewed and released to sites with training manual	
<input type="checkbox"/>	Study Start Up	Site meetings coordinated	
<input type="checkbox"/>	Site activation meeting	Face to face or webinar conducted with sites	
<input type="checkbox"/>	First site activated	Acknowledgement	
<input type="checkbox"/>	First patient accrued	Acknowledgement	
<input type="checkbox"/>	Last site activated	Acknowledgement	
<input type="checkbox"/>	Participant enrolment	Monitor recruitment statistics	
<input type="checkbox"/>	ANZCTR	Update recruitment and additional if required	
<input type="checkbox"/>	Funding body	Annual Report	
<input type="checkbox"/>	Communication	Ongoing communication with sites and participants	
Budget spend – Year 1 - \$			
<i>Insert Year</i>			
<input type="checkbox"/>	HREC annual progress report	Report submitted	
<input type="checkbox"/>	Regulatory and Ethics	Ongoing reporting (including AE's and SAE's)	
<input type="checkbox"/>	Participant enrolment	Participants registered in database	
<input type="checkbox"/>	Participant enrolment	Total patients registered in data base	
<input type="checkbox"/>	ANZCTR	Update recruitment and additional information if required	
<input type="checkbox"/>	Funding Body	Annual Report	
<input type="checkbox"/>	Communication	Ongoing communication with sites and participants	
Budget spend – Year 2 - \$			
<i>Insert Year</i>			
<input type="checkbox"/>	HREC annual progress report	Report submitted	
<input type="checkbox"/>	Regulatory and Ethics	Ongoing reporting (including AE's and SAE's)	
<input type="checkbox"/>	Last patient completed follow-up	Total Patients Completed Final Visit	
<input type="checkbox"/>	ANZCTR	Update recruitment and additional information if required	
<input type="checkbox"/>		Update recruitment and additional information if required	

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<input type="checkbox"/>	Trial close-out procedures sent to sites	Sites notified of close-out procedures	
<input type="checkbox"/>	Last trial site closed	Notification sent to site for close-out	
<input type="checkbox"/>	Funding Body	Annual Report	
<input type="checkbox"/>	Communication	Ongoing communication with sites and participants	
Budget spend – Year 3 - \$			
<i>Insert Year</i>			
<input type="checkbox"/>	Last trial site closed	Notifications sent to site for close-out – Data Lock	
<input type="checkbox"/>	Primary Endpoint	Initial Analysis completed	
<input type="checkbox"/>	Secondary Endpoint	Analysis completed	
<input type="checkbox"/>	ANZCTR	Update final information	
<input type="checkbox"/>	Communication to Sites	Study Results	
<input type="checkbox"/>	Communication to participants	Study Results	
<input type="checkbox"/>	Presentation and publications	Abstract submitted to conference and journal	
<input type="checkbox"/>	Funding Body	Final Report	
Budget spend – Year 4 - \$			