<table>
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<th>Investigational Product Study Phase</th>
<th>Typical study size</th>
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| **Phase 0: Human pharmacology (micro-dosing)** | ≈10-15 | Assess pharmacokinetics  
Involves dosing a limited number of participants with a limited range of doses for a limited period of time. | Specialist HREC; Bellberry (Adult) SCHN (Paediatric) |
| **Phase 1: Human pharmacology** | ≈ 10-100 | Safety and tolerance  
May involve the first administration to humans, usually to small numbers of healthy volunteers or to participants | Specialist HREC; Bellberry (Adult) SCHN (Paediatric) |
| **Study with a Phase I component** | ≈10-100 | Safety, efficacy and Maximum Tolerated Dose  
Phase I/II, or other variant with a phase I component, clinical trials test how well a certain type of disease responds to a new treatment. In the later phase component of the clinical trial, participants usually receive the highest dose of treatment that did not cause harmful side effects in the phase I part of the clinical trial. | Specialist HREC; Bellberry (Adult) SCHN (Paediatric) |
| ≥ Phase II | Typically >100 | Efficacy and safety | Local HREC |
| **Device Study Phase** | Typical study size | Objectives | HREC |
| **Early feasibility/ pilot study/ First in Human** | ≈10-30  
Usually involves a small group of human participants | A limited clinical investigation of a device early in development, typically before the device design has been finalised, for a specific indication, including marketed devices for a NOVEL clinical use. Exploratory investigations to determine preliminary safety and performance information to plan design modifications or provide support for a future pivotal study. | Specialist HREC; Bellberry (Adult) SCHN (Paediatric) |
| **Traditional feasibility study** | ≈30-100 | A clinical investigation commonly used to capture preliminary safety and effectiveness information on a near-final or final device design to adequately plan an appropriate pivotal study. | Specialist HREC; Bellberry (Adult) SCHN (Paediatric) |
| **Pre- or Post- Market (pivotal) study** | Typically >100 | Evaluate ongoing performance and safety | Local HREC |
Additional Guidance

- **NMA Exemption for Adult EPCTs in NSW:**
  NSW Health is excluding all adult early phase clinical trials from the National Mutual Acceptance (NMA) model. At this time, NSW Public Health Organisation (PHOs) sites will not accept interstate HREC reviews for ADULT EPCTs. All new ADULT EPCTs proposed to be conducted in a NSW PHO site, must be submitted to Bellberry HRECs for ethics review.

- **Paediatrics EPCTs in NSW:**
  NSW Health recognises that there is a small community of practice and high collegiality amongst paediatric clinical trial sites nationally. For multi-centred paediatric EPCTs, if an HREC hosted in a specialist paediatric tertiary hospital outside NSW has approved a paediatric EPCT, NSW PHO sites will continue to accept interstate HRECs' approval in these instances. However, it is important to note that paediatric EPCTs with a NSW PHO lead site are required to be submitted to SCHN HREC for ethics review.

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**Age Group within the Scope:**

**Bellberry HRECs:**
- Trials involving adults equal to and greater than the age of 18 years; or
- Combined paediatric and adult trials involving young people and adults equal to and greater than 16 years.

**SCHN HREC:**
- Trials involving only children and young people under the age of 18; and
- Combined paediatric and adult trials involving children and young people under the age of 16 and young adults up to the age of 25.