Clinical trial phase code N

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# Clinical trial phase code N

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| Identifying and definitional attributes |
| Metadata item type: | Value Domain |
| METEOR identifier: | 458406 |
| Registration status: | [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Standard 04/02/2015 |
| Definition: | A code set representing the phases of clinical trials. |

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| Representational attributes |
| Representation class: | Code |
| Data type: | Number |
| Format: | N |
| Maximum character length: | 1 |
|   | **Value** | **Meaning** |
| Permissible values: | 1 | Phase I |
|   | 2 | Phase II |
|   | 3 | Phase III |
|   | 4 | Phase IV |
| Supplementary values: | 9  | Unknown  |

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| Collection and usage attributes |
| Guide for use: | Generally, clinical research that involves the testing of a new drug or intervention progresses in an orderly series of steps, called phases. This allows the research to ask and answer questions in a way that results in reliable information about the drug and protects the patients.CODE 1   Phase IResearch testing a new drug or treatment with a small number of people for the first time to evaluate its safety, determine a safe dosage range, determine safe methods of administration, and identify side effects.CODE 2   Phase IITesting of a drug or treatment witha larger group of people to see if it is effective and to further evaluate its safety.CODE 3   Phase IIITesting of a drug or treatment with large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely. This phase will generally involve randomised control trials (RCTs).CODE 4   Phase IVStudies that are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations, side effects associated with long-term use, interactions with other interventions and for general surveillance of the intervention. Phase IV trials may involve thousands of participants. |

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| Source and reference attributes |
| Submitting organisation: | Cancer Australia |
| Reference documents: | US National Library of Medicine 2011. US National Library of Medicine, Bethesda, MD, USA. Viewed 27 July 2011, <http://www.nlm.nih.gov/services/ctphases.html>National Cancer Institute 2011. National Cancer Institute, Bethesda, MD, USA. Viewed 27 July 2011, <http://www.cancer.gov/clinicaltrials/education/what-is-a-clinical-trial> |

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| Relational attributes  |
| Data elements implementing this value domain: | [Person with cancer—clinical trial phase, code N](https://meteor.aihw.gov.au/content/458384)       [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Standard 04/02/2015 |