Person with cancer—clinical trial phase, code N

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# Person with cancer—clinical trial phase, code N

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| Identifying and definitional attributes |
| Metadata item type: | Data Element |
| Short name: | Clinical trial phase |
| METEOR identifier: | 458384 |
| Registration status: | [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Standard 04/02/2015 |
| Definition: | The phase of the clinical trial(s) in which the person with cancer is enrolled, as represented by a code. |
| Data Element Concept: | [Person with cancer—clinical trial phase](https://meteor.aihw.gov.au/content/458382) |
| Value Domain: | [Clinical trial phase code N](https://meteor.aihw.gov.au/content/458406) |

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| Value domain attributes |
| 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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| Data element attributes  |
| Collection and usage attributes |
| Guide for use: | Record the phase of each [**clinical trial**](https://meteor.aihw.gov.au/content/522854) the person with cancer entered throughout the entire course of treatment for cancer.The phase outlines the stage of clinical research that the trial is involved in, from phase I, the initial stage of testing in human subjects, to phase IV, surveillance of a drug or intervention after release for non-experimental clinical use.This item is completed when the person with cancer has been offered and accepted clinical trial entry. |
| Collection methods: | This information should be sought from the patient's medical record. |
| Comments: | Information regarding the types of clinical trials patients are enrolled in may have implications for access to, and the provision of, cancer services. |
| 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>> |
| Relational attributes |
| Related metadata references: | See also [Person with cancer—research trial type, code N](https://meteor.aihw.gov.au/content/458194)       [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Standard 04/02/2015 |
| Implementation in Data Set Specifications: | [Adolescent and young adult cancer (clinical) DSS](https://meteor.aihw.gov.au/content/432097)       [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Superseded 14/05/2015***Conditional obligation:*** Complete when [Person with cancer—research trial type, code N](https://meteor.aihw.gov.au/content/458194) equals 'clinical trial'.***DSS specific information:*** This item should be recorded for clinical trials relating to the initial course of treatment and clinical trials relating to the first recurrence of cancer where applicable.[Adolescent and young adult cancer (clinical) NBPDS](https://meteor.aihw.gov.au/content/599629)       [Health](https://meteor.aihw.gov.au/RegistrationAuthority/12), Standard 14/05/2015***Conditional obligation:*** Complete when [Person with cancer—research trial type, code N](https://meteor.aihw.gov.au/content/458194) equals 'clinical trial'.***DSS specific information:*** This item should be recorded for clinical trials relating to the initial course of treatment and clinical trials relating to the first recurrence of cancer where applicable. |