Person with cancer—clinical trial phase, code N

Exported from METEOR (AIHW's Metadata Online Registry)

Person with cancer—clinical trial phase, code N

Identifying and definitional attributes

Metadata item type:	Data Element
Short name:	Clinical trial phase
METEOR identifier:	458384
Registration status:	Health, 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
Value Domain:	Clinical trial phase code N

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

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 I

Research 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 II

Testing 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 III

Testing 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 IV

Studies 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.

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

Data element attributes

Collection and usage attributes

Guide for use: Record the phase of each **clinical trial** 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>

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Relational attributes

Related metadata references: See also Person with cancer—research trial type, code N
Health, Standard 04/02/2015

Implementation in Data Set Specifications: Adolescent and young adult cancer (clinical) DSS
Health, Superseded 14/05/2015
Conditional obligation: Complete when Person with cancer—research trial type, code N 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
Health, Standard 14/05/2015
Conditional obligation:

Complete when Person with cancer—research trial type, code N 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.