

Clinical trial phase code N

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Identifying and definitional attributes

Metadata item type:	Value Domain
METEOR identifier:	458406
Registration status:	Health , Standard 04/02/2015
Definition:	A code set representing the phases of clinical trials.

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 with a 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>

Relational attributes

Data elements implementing this value domain: [Person with cancer—clinical trial phase, code N](#)
[Health](#), Standard 04/02/2015