

Open Peer Review on Qeios

Group C/Treatment IND Protocol

National Cancer Institute

Source

National Cancer Institute. <u>Group C/T reatment IND Protocol</u>. NCI Thesaurus. Code C15478.

A means for providing compassionate use of investigational agents between the time that an agent has been shown to have anti-tumor activity and the time that drug becomes available on the market. Investigational agents that have been given Group C/T reatment IND designation by the FDA have reproducible efficacy in one or more specific tumor types. Such an agent is likely to alter the pattern of treatment of the disease and can be safely administered by properly trained physicians without specialized supportive care facilities. If a drug meets these criteria CTEP may initiate a formal application to the FDA to authorize Group C distribution for a specific indication. Such approval is not equivalent to formal FDA approval of effectiveness for this indication. Any registered investigator may receive a Group C agent.

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