

It's only a phase: Applying the 5 phases of clinical trials to the NSCR model improvement process

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NASA limits astronaut radiation exposures to a 3% risk of exposure-induced death from cancer (REID) at the upper 95% confidence level. Since astronauts approach this limit, it is important that the estimate of REID be as accurate as possible.

The NASA Space Cancer Risk 2012 (NSCR-2012) model has been the standard for NASA's space radiation protection guidelines since its publication in 2013. The model incorporates elements from U.S. baseline statistics, Japanese atomic bomb survivor research, animal models, cellular studies, and radiation transport to calculate astronaut baseline risk of cancer and REID. The NSCR model is under constant revision to ensure emerging research is incorporated into radiation protection standards. It is important to develop guidelines, however, to determine what new research is appropriate for integration. Certain standards of transparency are necessary in order to assess data quality, statistical quality, and analytical quality. To this effect, all original source code and any raw data used to develop the code are required to confirm there are no errors which significantly change reported outcomes.

It is possible to apply a clinical trials approach to select and assess the improvement concepts that will be incorporated into future iterations of NSCR. This poster describes the five phases of clinical trials research, pre-clinical research, and clinical research phases I-IV, explaining how each step can be translated into an appropriate NSCR model selection guideline.