**Grant Number**: N/A

**Sponsor: CRCTU**

**Project title**: Dose-level toxicity and efficacy outcomes from dose-finding clinical trials in oncology

This dataset contains information on the outcomes observed at each dose-level in a large number of dose-finding clinical trials in oncology. These trials typically seek to identify a maximum tolerable dose or a recommended phase 2 dose. A common rule-based method for conducting such trials is the 3+3 algorithm. A common model-based alternative is the continual reassessment method (CRM). Each of these methods assumes that as dose is increased, the probabilities of toxicity and efficacy will each increase monotonically. If this assumption is violated, both methods may recommend inappropriate doses. For instance, if the probability of efficacy does not increase in dose but the probability of toxicity does, the 3+3 and CRM designs may recommend a dose that is unjustifiably high. The same is true of any design that assumes that "more is better". We collated this dataset to investigate the appropriateness of the monotonicity assumptions in dose-finding clinical trials.

See https://github.com/brockk/dosefindingdata for more information.

**The following files have been archived:**

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| File name | File description (Short description of content, sample size, format, any linking between different types of data, i.e. survey and interviews/focus groups) |
| Database\_v1.3.xlsx | Database of outcomes extracted from phase I clinical trial manuscripts to investigate evidence supporting the common assumptions that probabilities of toxicity and efficacy increase monotonically in dose. |
| Database.xlsx  Database\_v1.1.xlsx  Database\_v1.2.xlsx | Previous versions of the file Database\_v1.3.xlsx |
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**Publications based on this data:**

Brock, K., Homer, V., Soul, G., Potter, C., Chiuzan, C., & Lee, S. (2020). Is more better? An analysis of toxicity and response outcomes from dose-finding clinical trials in cancer. medRxiv.; doi: https://doi.org/10.1101/2020.08.18.20177212