PO-09

Direct and surrogate benefit in cancer clinical trials

Marcin Waligora

Jagiellonian University Medical College, Poland

Clinical trials in oncology assess the safety, efficacy, and adverse effects of novel cancer therapies. The high toxicity of the tested substances renders clinical trials in oncology particularly challenging. To fulfill adequate risk/benefit ratio requirements for these trials, many regulatory and methodological solutions were adapted. For example, unlike in other types of clinical trials, in phase 1 cancer trials, participants are not healthy volunteers but patients with cancer who have exhausted standard treatment.

Exposing participants of cancer trials to highly toxic agents must be weighed by the importance of the trials' objective, a promise of high benefit for participants and significant social value of these trials. In the presentation, I will evaluate the nature and ways of measurement of benefit in clinical trials in oncology. I start from an analysis of clinical endpoints used in these trials and test if they may be defined as the direct benefit. Subsequently, I evaluate therapeutic dose in trials as an indicator of direct benefit for participants. I will also reflect on alternative benefits for the trials' participants. Finally, I highlight the challenges associated with harvesting data about benefit from clinical trials.

Funded by the National Science Center, Poland, UMO-2021/41/B/HS1/01123.