VIRTUAL CLINICAL TRIALS

Mark Parker*

Zem Solutions Ltd., Belgrade, Serbia

*mark@zem-solutions.com

Double Blind randomised controlled trials are the gold standard in estimating the clinical effect of medications, with pivotal phase 3 clinical trials forming the foundation a total revolution in healthcare decision making over recent decades. However, such trials are prohibitively expensive to conduct and the probability of a successful launch of a new medicine ranges from only 3% in nervous system disorders to 16% in anti-infectives (1). By considering Markov and Discrete Event Simulation models, now used extensively in post launch decision making globally (2), it is possible to conduct "virtual trials" at all launch phases to robustly analyse medications and their value as treatments.

References

1. Dowden H, Munro J. Trends in clinical success rates and therapeutic focus Nature reviews. Drug discovery vol. 18,7 (2019): 495-496
2. Mauskopf, J. Meeting the NICE requirements: a Markov model approach." Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research vol. 3,4 (2000): 287-93.

VIRTUELNA KLINIČKA ISPITIVANJA

Mark Parker*

Zem Solutions d.o.o, Beograd, Srbija

*mark@zem-solutions.com

Dvostruko slepa randomizovana kontrolisana ispitivanja su zlatni standard u proceni kliničkog dejstva lekova, sa ključnim kliničkim ispitivanjima faze 3 koja čine temelj potpune revolucije u procesu donošenju odluka u zdravstvu tokom poslednjih decenija. Međutim, takva ispitivanja su izuzetno skupa za sprovođenje, a verovatnoća uspešnog lansiranja novog leka kreće se od samo 3% kod poremećaja nervnog sistema do 16% kod antiinfektivnih lekova (1). Uzimajući u obzir Markovljeve i modele simulacije diskretnih događaja, koji se sada globalno koriste u velikoj meri u procesu donošenju odluka nakon lansiranja leka (2), moguće je sprovesti „virtuelna klinička ispitivanja“ u svim fazama lansiranja kako bi se robusno analizirali lekovi i njihova vrednost kao terapije.

Literatura

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