Accelerated virtual evaluation

Increased threat to patient safety

The evaluation of a new drug follows a process which has been established over decades and in the light of many health disasters: preclinical studies, in particular animal studies; then initial trials in healthy volunteers (phase I); then the experimental phase with non-comparative trials and the first comparative trials in a limited number of patients (phase II); and finally comparative trials against reference treatments or placebo aimed at confirming hypotheses (phase III).

In the 1990s, it was acknowledged that the efficacy of a new drug should be proven by at least two comparative trials against the reference treatment. For some years now, however, market authorisation (MA) is frequently granted on the basis of a single phase III comparative trial, or even phase II trials, as is the case for *daratumumab* as monotherapy for multiple myeloma (see *Prescrire International* N° 188, December 2017). A race is underway to obtain ever more rapid MA, which is jeopardising the reliable evaluation of the harm-benefit balance of drugs.

If acceleration is the prime objective, then let's accelerate! One might as well skip the healthy volunteer studies phase (which is not useful for judging efficacy), and also the animal studies phase, which would spare animal suffering. Why not go straight to approval based on virtual drug modelling, tested by algorithms based on virtual patients, just like video games?

However, in video games, the participants have several lives, unlike patients exposed to drugs.

Accelerated virtual evaluation of virtual efficacy = real acceleration of the threat posed to patient safety.

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