Three 2023 news regarding ‘Statistics in in-vitro Toxicology’
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I like to discuss some consequence from the recently released:
i) FDA 2\textsuperscript{nd} modernization act: no-vivo data more needed
iii) M. Hayashi “Statistical significance” and other important considerations in genotoxicity safety testing. Mut Res. (2023)

The old contradiction between significance and relevance breaks out again in full. There is none- only inappropriate formulated tests. Therefore are recommended:

i) non-inferiority tests within the proof-of-safety framework instead of point-zero-H0 tests within the common used proof-of-hazard,

ii) a delta-value threshold of 'yet to be tolerated effect’ is inherently needed.

The definition of the randomized unit is essential in inference. Based on the paradigm ‘a rat is a little man’ it is available in in-vivo bioassays. It is not obvious in in-vitro assays- with dramatic consequences. Assay-specific proposals are discussed.

Sometime k-fold is used for interpretation in in-vitro assays. But the statical tests based on the difference-to-control effect size. This basic contradiction can be overcome be using ratio-to-control tests and confidence intervals.

Related examples are demonstrated and their evaluation by means of CRNA packages.