Thoughts on animal-free drug development

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If the pharmaceutical industry were to develop medicine for patients without using animals in the drug development process the non-animal methods off course need to ensure that the safety of the patients is not compromised. The non-animal methods need to be equally good as the present in vivo models. With the recent years investments in micro physiological systems (MPS) a future without use of animals is no longer just an unreachable future. However, for this to happen the current legislation requiring animal data needs to be changed as well.

Currently we are already applying alternative approaches in the early phases of drug development. This is for instance human immune cells for in vitro assays when testing potency of drugs under development. Artificial intelligence (AI) models can be used to predict safety of drugs and to some extent to predict metabolism and excretion of drugs. Human stem cells can be used to predict teratogenicity, and bacteria and human lymphocytes can be used to predict genotoxicity i.e., cancer risk. There are many ongoing activities within the field of “Organ-on-a-chip” potentially leading to “Human-on-a-chip”. But for all the mentioned model systems regulators require to have them followed-up by testing in animals as they are not 100% predictive. At LEO Pharma where we have a dermatology focus, we can in some cases predict efficacy and pharmacodynamics (PD) of a drug via application on freshly isolated skin from patients after plastic surgery at Herlev Hospital.

Where we find it challenging in regard to an animal free future in drug development is the repeated dose tox studies, where adverse events during chronic dosing of a drug candidate is evaluated. Currently there doesn’t exist animal-free models with the necessary complexity to evaluate adverse events on all organ systems after chronic exposure of a test compound.