Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

developmental exposure and may reveal effects on immune suppression or stimulation. The current challenge is that this cohort is only included if triggers are presented. While only observational (not functional) immune endpoints, in adult animals, are available from mandatory regulatory testing, this may lead to lack of regulatory testing of putative developmental immunotoxicity since mechanisms and sensitivity may strongly differ between adult and developmental exposure.

The increase in early-life prevalences of immune diseases as well as other disease states where inflammatory processes play a central role illustrates that we are not sufficiently protecting the population from detrimental exposures during development. In addition to the need for more knowledge on the ability of the DIT EOGRTS cohort to identify immunotoxic compounds, there are also a knowledge and testing gap for other arms of immunotoxicity as hypersensitivity and autoimmunity.

Identification of predictive regulatory tests has probably been hampered by the complexity of the fine-tuned immune system and its adverse outcomes. Recent technological and biostatistical advances allow for high dimensional assessment of immune function and systems immunology approaches. Such approaches hold promise for future advancements in identifying mechanisms and causal relationships in (developmental) immunotoxicology. The combination of experimental and epidemiological studies is expected to be important for future immune toxicity evaluations.

https://doi.org/10.1016/j.toxlet.2022.07.098

S-10-04
Future perspectives of alternatives to developmental immunotoxicity testing

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The development of non-animal New Approach Methods (NAMs) has been widely acknowledged as a critical need for toxicity testing. Although critical windows of developmental immunotoxicity (DIT) have been defined by the field, DIT testing at the moment is intimately linked to the use of whole animal studies with inherent limitations in translatability to humans. Sensitive *in vitro* assays are hampered by the complex nature of the effects and the partially missing information on interrelationships in the human system, especially during the developmental period. Clinical information on the effects of drugs and other exposures on the developing immune system *in utero* are scarcely available. Unfortunately, the status of *in vitro* and other alternative assays available for DIT screening is unclear as few alternative approaches have been developed and adapted by the greater toxicology community. Through expert workshops the "International Working Group on Alternatives to Developmental Immunotoxicity Testing" is identifying and addressing critical knowledge gaps in the field of alternative DIT, which will be highlighted in this presentation. First, the need for alternative DIT testing strategies will be discussed from applied and regulatory end-user perspectives. Second, an updated and refined network of key molecular and biological events in developmental immunology that are important to assess during DIT testing will be presented. Current efforts to translate scientific advances into adverse outcome pathways (AOP) that can inform `regulatory hazard or risk assessment will be discussed. Examples of existing alternative strategies that are useful and appropriate for DIT testing will be provided. In addition, areas in need of development of alternative DIT models and tests will be highlighted through the introduction of a novel framework to encourage the refinement and development of new alternative test methods suitable for screening of (large numbers of) DIT compounds. Finally, a future outlook on how ground-breaking innovations and state-of-the art technologies can benefit the switch to alternatives to DIT will be presented. The ultimate goal is to develop a methodology for alternative DIT screening and develop test guidelines that can be incorporated in OECD guidance documents.

https://doi.org/10.1016/j.toxlet.2022.07.099

S-11 | Toxicology for Covid19 vaccines: industry, regulatory and CRO perspectives

S-11-01
Covid19 vaccine toxicology: introduction and CRO experience/ perspectives

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The pandemic needed the rapid development of a SARsCov2 vaccine, without impacting on safety and despite Covid being a new disease, with limited understanding of the animal models, unknown correlates of protection and challenges of biosafety levels. mRNA vaccines, which were previously in the therapeutic domain, also brought some additional considerations. Despite these challenges, the first person to be vaccinated was just over a year after the first case was identified, on 29th December 2020. This presentation discusses the requirements for a non-clinical program for a SARsCov2 vaccine, linking how vaccines work and addressing potential safety concerns from first in human to license. Woven into the presentation will be a discussion on models and species selection, as well as how we supported speeding development up and kept up with an adapting regulatory environment. We also needed to educate and support new players (both manufacturers and scientists) who were often more familiar with the principles of ICH than the WHO guidelines (the key guidelines for prophylactic vaccine). Finally, we will provide an update on how we are continuing discussions on models and species selection, as well as briefly mentioning the new WHO guidelines for mRNA vaccines.

https://doi.org/10.1016/j.toxlet.2022.07.100

S-11-02
Regulatory considerations for non-clinical studies for COVID-19 vaccines: US FDA perspective

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The Food and Drug Administration (FDA) plays a critical role in protecting the United States from threats such as emerging infectious diseases. These threats include the pandemic resulting from the coronavirus disease-2019 (COVID-19) - caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). One of FDA's primary objectives in reviewing an Investigational New Drug application are to assure the safety and rights of enrolled patients or healthy volunteers in clinical trials. Stringent nonclinical evaluation of investigational vaccines, before testing in humans, is a critical factor in the evaluation of the vaccine's safety. Response to a pandemic outbreak warrants an efficient approach to development of safe and