innovative health initiative

Outcome of the IHI JU Science and Innovation Panel on ideas submitted for potential IHI topics

Reference number of the idea: N° TI_001220

In vivo data redefined: Empowering Drug Discovery with Advanced Insights Through the Right Data Frameworks and Standards

Overall opinion

The idea aims at improving the discovery and development of new medicines by leveraging AI-driven frameworks and standards. At this stage, the currently formulated idea is not yet mature for obtaining a favourable opinion from the SIP for the following reasons:

- Frameworks and methodologies need to be defined and to take into consideration the rapid nature of AI technology by addressing the iteration cycles of the envisaged models and data
- Limitations of exchange of nonclinical data across sectors need to be identified and any activities need to build on available standards, such as the Standard for Exchange of Nonclinical Data (SEND)[1]
- Appropriate criteria for the reduction and replacement of animal studies through new approach methodologies (NAMS) should build upon existing initiatives such as by the European Commission[2], by EMA,[3] AnimalGAN[4] developed by the FDA or the "Virtual Second Species" project within the NC3Rs toxicology programme[5].

Regulatory fit of the dynamics of ML and AI have to be considered based on the learnings from previous and ongoing IMI/IHI projects and Horizon Europe initiatives.

[1] *An implementation of the CDISC Standard Data Tabulation Model (SDTM) for nonclinical studies, which specifies a way to present nonclinical data in a consistent format (https://www.cdisc.org/standards/foundational/send)*

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14281-Animal-testing-in-chemical-safety-assessments-Commission-roadmap-to-phase-it-out_en

[3] https://www.ema.europa.eu/en/human-regulatory-overview/research-development/ethical-use-animals-medicine-testing

[4] *Chen, X., Roberts, R., Liu, Z. et al. A generative adversarial network model alternative to animal studies for clinical pathology assessment. Nat Commun 14, 7141 (2023). https://doi.org/10.1038/s41467-023-42933-9*

[5] *https://nc3rs.org.uk/news/ps16m-awarded-develop-virtual-second-species*