



TITLE: ONITH: An Ontology-based Non-clinical Integration and Term Harmonization Pipeline facilitating Data Reuse in 3R

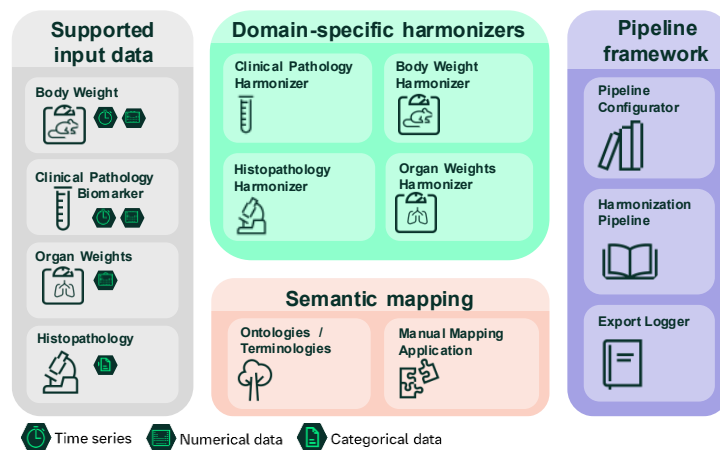
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ABSTRACT: Animal studies continue to play a critical role in drug development as they uniquely capture the physiological complexity required to elucidate drug mechanisms and safety profiles^[1]. However, in alignment with the 3R principles (Reduce, Refine, Replace), there is growing ethical and regulatory commitment on minimizing animal use. As part of this effort, the reuse of existing data has emerged as a potential strategy to support the transition toward more data-driven approaches in drug development - a direction that is increasingly supported by regulatory authorities as a viable opportunity to reduce the number of animal studies^[2]. Data reuse offers the opportunity to extract value from the repositories of historical animal data generated during previous drug development programs, a resource that has remained largely underutilized to date. Its potential to generate biological insights through cross-study computational modeling is currently primarily decelerated by the lack of comparability and standardization across these often descriptive and heterogeneous historical datasets^[3]. To address this, we developed an ontology-based non-clinical integration and term harmonization pipeline (*ONITH*), a Python-based tool designed to harmonize and consolidate historical animal study data into a unified dataset while ensuring compliance with established data standards for cross-study computational modeling. *ONITH* offers standardized yet adaptable workflows tailored to data domains typically collected in animal studies. It is implemented as an intuitive human-in-the-loop pipeline that is grounded in biomedical ontologies and enables interactive incorporation of expert knowledge. Through *ONITH*, we aim to facilitate systematic data reuse and ultimately contribute to the reduction of future animal studies.



Modular package architecture of ONITH. Supported input data domains include body weight, clinical pathology biomarker, organ weights and descriptive histopathology data.

Keywords

Drug Development; Data Harmonization; Data Reuse; 3R; Biomedical Ontologies

References



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