CONTRACT CONCEPT REVIEW

NTP Board of Scientific Counselors Meeting
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Concept title: Support for Toxicological Data for the NTP

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Purpose

The purpose of the Support for Toxicological Data Contract is to support the acquisition and housing of data from NTP toxicological studies, the integration of data across studies and toxicological domains, and the presentation of toxicological data in a meaningful format for use in decision-making by NTP scientists, other government agencies and the public at large.

Background and Significance

The NTP conducts studies to evaluate the toxicity of various environmental agents, and has incorporated a wide range of study designs that encompass a broad array of endpoints into the testing program. The NTP conducts and reports toxicology studies using a number of different study designs which include studies aimed at assessing reproductive and developmental toxicity, neurotoxicity and immunotoxicity, short term studies aimed at assessing changes in gene expression, and high-throughput studies of cultured cells, in addition to prechronic and chronic toxicity studies. This increasing diversity and complexity of study designs results in an increase in the amount and variety of data received by the NTP. The NTP must capture all types of data from individual animals used in toxicological studies in a central data system and house the data in a form compatible with data mining across studies. The NTP requires support as to how best to acquire these data while preserving the scientific meaning and information content.

The NTP recently has licensed Provantis$^®$, a commercial data collection system from Instem, LLC. Provantis$^®$ permits the NTP contract laboratories to collect data from reproductive and developmental toxicology, neurotoxiciology and immunotoxicology studies in addition to prechronic toxicity, chronic toxicity and carcinogenicity studies. Each NTP endpoint must be re-created in Provantis$^®$, calculations added, and then Provantis$^®$ tables designed with proper statistics to report the endpoints. Study logistics must also be considered when using Provantis$^®$ to ensure that the resulting work schedule and endpoint collection procedure are feasible. All these tasks require an understanding of both Provantis$^®$ and the realities of study logistics for the ideal use of Provantis$^®$ to collect and report NTP data.

In addition to collecting in-life data in Provantis$^®$, the NTP uses other data systems to collect study data. The NTP requires the assistance of contract staff with toxicological expertise to organize the data, ensure syntactic and semantic accuracy and completeness in the data, write applications to load these data into the NTP data system, and then enhance the NTP data

system to present them for visualization and interpretation by NTP staff. When study data are acquired, the metadata about the study are also needed to ensure that the study data can be properly interpreted and subsequently used for data mining and meta-analysis.

As new and complex data are acquired by the NTP, new strategies are needed in order to optimize data organization and management within the NTP data system to ensure that NTP scientists and the public can access NTP study results efficiently and accurately. This requires research with different strategies for data management and data warehousing and then development of successful approaches into new applications to present the data for use. The NTP requires the support of data scientists to perform this research and development.

In summary, the NTP requires assistance from scientists familiar with toxicological studies to provide recommendations and computer support for the acquisition, analysis, visualization, interpretation and reporting of diverse types of toxicological data relevant to the effects of environmental exposures on human health.

The new Contract shall:
- Ensure that NTP toxicological endpoint data, study meta-data and summary / conclusion data are housed efficiently, accurately and completely at the NTP in a manner that allows NTP scientists to interrogate the integrated data and efficiently reach informed decisions about the hazards associated with exposure to environmental toxicants.

- Support NTP staff and contractors with the use of Provantis$^{®}$ for data capture and data reporting, and supply staff with appropriate training to perform validation of methods and/or components of Provantis$^{®}$ for use by an NTP contract laboratory.

- Provide training materials and prepare materials for publication / presentation at the request of the NTP.

- Maintain, enhance and extend current functions of the NTP data system and, as toxicological data or information technologies change, respond in a manner that maintains data integrity and continuity of function of the NTP data system.

- Ensure that NTP data from toxicological studies are available in an accurate, effective and biologically meaningful context for decision-making by NTP scientists, other government agencies and the public at large

Summary of Proposed Statement of Work
The Support for Toxicological Data contract is a new requirement that will provide the necessary resources to ensure accurate and complete data capture, house the data in the NTP data system in a manner compatible with data integration and meta-analysis, and prepare data visualization and presentation methods to support effective interpretation. This contract will facilitate the use by the NTP of an array of study designs and technologies to produce data to

address questions of the effects on environmental agents on human health from reproductive and developmental effects to questions of neurological and immunological toxicity as well as carcinogenicity and toxicity.