

Contract Concept Review for Chemistry Support for the Division of Translational Toxicology, NIEHS

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History and overview of the requirement

- Chemistry support is essential for the Division of Translational Toxicology (DTT) research activities
- Scope and breadth of the support required exceeds the resources available at NIEHS
- Therefore, chemistry support has been obtained through contract resources for over 40 years
 - The type of support has evolved over the years to align with the Division needs



Chemistry support falls under nine broad functional areas

 Each area covers multiple activities to allow flexibility to support broader study types

1. Logistics & Handling

Activities related to procurement and handling test articles 2. Characterization

Activities related to identification and purity determination of a test article 3. Formulation

Activities related to formulation of test articles for testing in vitro and in vivo 4. Biosample Analysis

Activities related to determining concentration of analyte(s) in biological matrices 5. Animal Studies

Activities related to determining ADME and TK behavior of test articles

ADME = Absorption, distribution, metabolism, and excretion TK = Toxicokinetics



Chemistry support falls under nine broad areas

6. Special Studies

Covers a range of activities

e.g., determining the partition coefficient of an analyte between two matrices; screening of multiple botanical lots to select a lot for testing

7. Omics

Activities related to exposomics, proteomics, and metabolomics

8. In Vitro Assays

Activities related to determining ADME properties of test articles in vitro

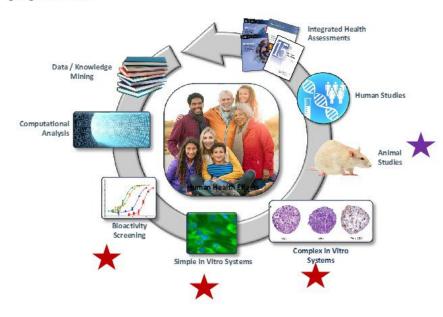
9. MHTS Activities

Activities supporting medium to high throughput toxicity screening

ADME = Absorption, distribution, metabolism, and excretion MHTS = Medium to high-throughput screening



Broader chemistry support across the DTT translational toxicology pipeline

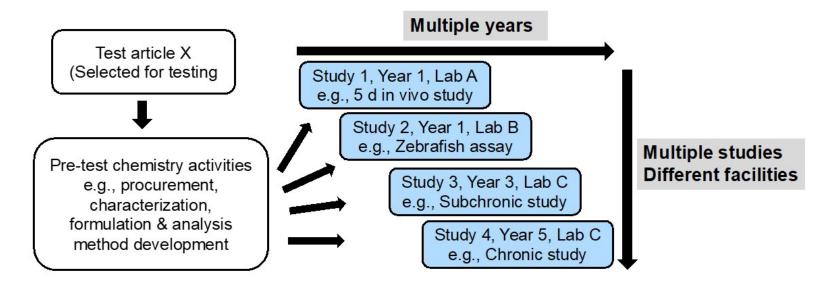


- In vitro toxicology study support ★
- In vivo toxicology study support ★
- In vitro and in vivo ADME /TK study conduct



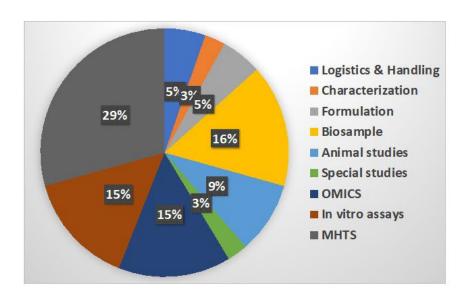
Chemistry support typically will be obtained on a per test article basis

 Allows support to be applied to multiple studies conducted at different times and different research facilities





Anticipated support varies per functional area



- MHTS support is the highest ~29%
- Omics, In vitro assays and Biosample analysis areas are ~15%
- Animal studies are ~9%
- Other areas are 3-5%



Charge to the Board of Scientific Counselors

- The BSC members are asked to review the contract concept for overall value and scientific relevance, as well as for fulfilling NIEHS' goal of protecting public health. Consideration should be given to:
 - · The significance of the goals of the proposed research activity
 - The availability of the technology and other resources necessary to achieve those goals
 - · The extent to which there are, practical scientific or clinical uses for the expected results
 - The adequacy of the proposed methodology
- The DTT seeks approval from the BSC to continue this type of activity using a contract mechanism

