Topics of Interest to the Grantees of NCI Developmental Therapeutics Program

OMB No.: 0925-0642
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* Required

1. Where does your research interest reside with respect to the following stages of drug discovery and development? (check most appropriate) *

- ○ Early Drug Discovery
- ○ Preclinical Development
- ○ Clinical Development
- ○ Other

2. Which of the following general issues in drug development would be valuable to your efforts? *

(drag the topics or use the arrow to rank the topics based on the level of interest)

Understanding key milestones and components of a product-specific Investigational New Drug (IND)- package and regulatory requirements for an IND-filing

Creating a product development plan for a therapeutic candidate (e.g. development strategies, team members composition, target product profile creation)

Additional considerations for developing a therapeutic candidate for clinical entry, e.g., targeted indication and patient population, predictive biomarker(s) for patient selection, and understanding the proposed mechanism of action

3. What non-clinical toxicology topics would you like to learn more about? *

(drag the topics or use the arrow to rank the topics based on the level of interest)

Typical safety studies that should be conducted for oncology agents and toxicities that may hinder development

Differences between non-Good Laboratory Practice (GLP) toxicity, GLP toxicology, and safety studies with regards to purpose, study design, and endpoint

Designing an appropriate toxicology studies for an agent including model, dose, and route of administration

For immuno-oncology agents: appropriate assays and endpoints for the toxicology studies to assess immune-related adverse events (e.g. cytokine release syndrome, neurologic toxicity)

4. What aspects of chemistry, manufacturing, and analysis would be of value to you? *

(drag the topics or use the arrow to rank the topics based on the level of interest)

- Challenges in scaling up laboratory processes to manufacture enough quality drug product for a clinical trial
- Assays and analytical methods needed to generate a certificate of analysis for release of a therapeutic candidate
- The importance of Good Manufacturing Practice (GMP) for your therapeutic candidate
- For small molecules: polymorphic forms, stability, and solubility, and when the development of a clinical formulation should be initiated
- For biologics: cell line development, upstream & downstream process development, and regulatory considerations

5. Other key topics for preclinical development *

(drag the topics or use the arrow to rank the topics based on the level of interest)

Demonstrating sufficient evidence that pharmacologic/therapeutic activity of the agent has been shown in disease relevant models

Preclinical pharmacokinetics/pharmacodynamics: study design, data interpretation, and application

Considerations for translation of combination therapies, including immunotherapies

Unique considerations and requirements for pre-clinical development of immunotherapeutic agents

Indicators of a good contract research organization (CRO) for performing chemical manufacture/analysis, pharmacology, toxicology, and formulation work

6. Other topics of interest to you (please comment)

Enter your answer

7. What format(s) do you prefer to receive the information? (check top two)

- [ ] Virtual session-based workshop (3-4 hours across multiple days)
- [ ] Webinar series (discrete topics in 1-2 hours monthly)
- [ ] Videocast of session-based lectures followed by virtual discussion meeting
- [ ] In-person workshop

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