



NIMH Toxicology and Pharmacokinetic Support Questionnaire

Priority for assignment of NIMH resources will be based on which agents have the most complete data packages; i.e., investigators who can provide information in all of the below areas will be given highest priority.

Requests for GLP studies will require additional information and another level of review.

Please include the following information on the candidate test agent:

1. Information regarding the binding affinity (K_i) of the unlabeled ligand at cloned human receptors to assess potency, selectivity, and its interactions with other receptors.



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2. Information on lipophilicity measurements.



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3. Information on MTD data by iv route (rodents) or information about iv dose range finding studies.



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4. Information regarding in vitro autoradiography studies in the brain (rodents).



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5. Information regarding in vivo biodistribution studies: i.e. analysis of tissue uptake and/or washout (%ID, injected dose) at multiple time points in various brain regions (rodents).



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6. Information regarding competitive inhibition studies (rodents): i.e. IC₅₀ determinations for antagonists.



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7. Information on in vivo metabolism studies (rodents): i.e. HPLC analysis of parent compound and metabolites in whole brain at multiple time points.



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8. Information on in vitro metabolism studies in rat and human hepatocytes.



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9. Information on ex vivo autoradiography studies(rodents): analysis of non-specific binding in the brain at multiple time points after radioligand injection.



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10. Information regarding in vivo pharmacology and/or PET studies (primates): i.e. competition & placement studies with agonists and antagonists, non-specific binding, in vivo modeling to determine K_d and B_{max} , in vivo metabolism; test/retest reliability.



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11. Information regarding dosimetry studies (rodents): i.e. whole body distribution to measure organ exposure, dosimetry calculations to estimate maximum injected radiation dose (MIRD) in humans; %ID determined in brain, heart, liver, lung, kidney, spleen, ovaries, testes, adrenal.



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12. Bioanalytical methods for detection of plasma levels.



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13. Analytical methods development.



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14. Formulation of compound.



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15. Source of financial support for the proposed research.

Please return this completed form by [e-mail](#).