Pre-IND Consultation Program

What is the Office of Antimicrobial Products (OAP) Pre-IND Consultation Program?

Established in 1988, the Office of Antimicrobial Products (OAP) Pre-Investigational New Drug Application (Pre-IND) Consultation Program is designed to facilitate and foster early communications between the divisions of OAP and potential sponsors of new therapeutics (drugs, monoclonal antibodies, and therapeutic proteins) for the treatment of bacterial, fungal, and viral infections, opportunistic infections, emerging infections (including naturally emerging diseases and potential biothreat agents), topical microbicides directed at prevention of HIV transmission, and transplant rejection. ([21 CFR 312.82(a)](http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?Title=21&Part=312&Section=82&Type=Text)).

Pre-IND advice may be requested for issues related to data needed to support the rationale for testing a drug in humans; the design of nonclinical pharmacology, toxicology, and drug activity studies, including design and potential uses of any proposed treatment studies in animal models; data requirements for an Investigational New Drug (IND) application; initial drug development plans, and regulatory requirements for demonstrating safety and efficacy.

We encourage all potential drug sponsors or investigators to examine the information available from this site and to initiate contact with us as early in the drug development process as possible, so that they will have the opportunity to consider our recommendations in planning preclinical and clinical development programs.

How Do I Obtain Further Information Regarding the Program?

Please contact the appropriate Division for further information and specific contact information.

The Division of Antiviral Products (DAVP) is responsible for:

- HIV, AIDS and prevention of HIV transmission
- Viral hepatitis
- Herpesviruses
- Topical microbicides
- Emerging viral infections (including but not limited to respiratory viruses, zoonoses, and potential biologic threat agents)
- Other non-life-threatening and life-threatening viral infections

For more information, please visit the [DAVP Pre-IND Web page](/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/ucm077776.htm).

The Division of Transplant and Ophthalmology Products (DTOP) is responsible for:

- Solid Organ Transplant Products
- Ophthalmology Products

For further information regarding the Pre-IND process for the Division of Transplant and Ophthalmology Products, please call 301-796-1600.

The Division of Anti-Infective Products (DAIP) is responsible for:

- Most systemic and topical antimicrobials
- Topical antiseptics
- Drug products for the adjunctive treatment of sepsis
- Drug products for treatment of Lyme disease

For more information please call 301-796-1400.

**Note:** Pre-IND interactions should be considered as preliminary communications based on early development information, and will generally take the form of written comments that may be supplemented by teleconferences or meetings as needed and appropriate. Additions or modifications to these communications may arise as additional information becomes available, during follow-up pre-IND interactions or when an IND is established.

For the Pre-IND Consultation Program, please contact the appropriate division referenced on the CDER Pre-IND Consultation Contact List

Pre-IND Contact List

- [Pre-IND Consultation Contact List](/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf) (PDF - 49KB)

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