Drug Discovery: Preclinical Research Development (2-10 years)

Early Stage Preclinical Development

Protection/Agreements

Non-GMP drug

Need to obtain drug (from external sources)

MTA in place and/or IP secured if needed?

No

Preclinical Testing Research

Yes

Need to formulate drug (from internal sources)

Contact OTRS

- Determine preliminary formulation
- Validate methods: bioanalytical/analytical
- Perform in vivo testing (PK metabolism, dose range-finding, determine efficacy)

UWCCC Shared Resources can help with these functions contact OTRS if help needed.

Late Stage Preclinical Development

Preclinical Testing Research

Pre-IND Protocol Development

- Determine preclinical toxicity testing for IND/pharm tox
- Pre-IND meeting (FDA)
- Prepare Pre-IND document
- Prepare draft clinical protocol

Drug Manufacturing

- cGMP grade manufacturing of starting material
- Manufacture clinical formulation
- Chemistry, Manufacturing and Controls (scale-up manufacturing)
- Certificate of Analysis (proof of product characterization)
- Creation of CMC dossier (in addition to preparing the Investigator’s Brochure)

Pharmacology/Toxicology

- Finalize the preclinical toxicology protocol
- Perform necessary preclinical toxicology in animals
- Perform necessary PK testing in animals
- Prepare pharmacology/toxicology section for the IND submission
- Prepare final reports and finalize the Phase 1 Clinical Protocol(s)

Clinical Protocol/IND Submission

Go/Hold Decision

FDA