Role of the Office:

Provide integrated support from early drug discovery through clinical trials:

**Medicinal Chemistry**: tool compound synthesis
**Computer-Aided Drug Design (CADD)** Virtual lead identification using target-based & ligand-based database screening
**Assay development and screening** Biochemical and assay development support for putative therapeutic targets
**In vitro ADME Screening** metabolic stability in plasma, liver microsomes, S9, & hepatocytes, permeability, Pgp efflux
**Pharmaceutical Manufacturing & Enabled Clinical Trial Formulations**: Optimized non-sterile formulations
**Advanced Protein Characterization for Therapeutic Protein Development** characterization of sequence variants & posttranslational modifications for proteins, antibodies, & antibody-drug conjugates
**Biologic Products Development Program** development & testing of cell lines, gene vectors, peptides; GMP
**Clinical Drug Development Unit** design of first-in-human- Ph2 proof-of-concept trials, planning sample & data collection, data management and analysis, support of pre-IND, IND, & IRB applications
**Pharmacometrics** quantitative disease, drug, & trial modeling to inform drug development
**In Vivo Pharmacokinetics (PK) & Bioanalysis** In vivo PK in rodents, swine, & primates via various routes
**Biomarker**: **Imaging** integrated use of in vitro, pre-clinical, & clinical imaging methods
**Biomarker**: **Metabolomics** global metabolic profiling & stable isotope-13C and/or 15N-labeled. Lipidomics analysis
**Biomarker**: **Proteomics** protein biomarker development, verification, validation; technology to maximize coverage of key proteomes, quantitative mass spectrometry

Drug Discovery and Development (D3) Program

D3 is a collaboration between Johns Hopkins University and University of Maryland

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Services Provided:

- **Discovery & Early Development**
  - Medicinal chemistry
  - Drug assay development
  - Biomarker development (imaging, proteomics, metabolomics)
  - ADME/Pharmacokinetics
  - Animal Pharm/Tox (nonGLP)

- **Pharmaceutics & Regulatory**
  - Pharmaceutical development (drugs, proteins, biologics)
  - GLP-manufacturing
  - GLP Pharm/Tox
  - Regulatory (IND and IRB)

- **Clinical Development**
  - Pharmacometrics
  - Phase 0/I FIH/PK/PD/Tox
  - Drug assay application
  - Biomarker application (imaging, proteomics, metabolomics)