

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

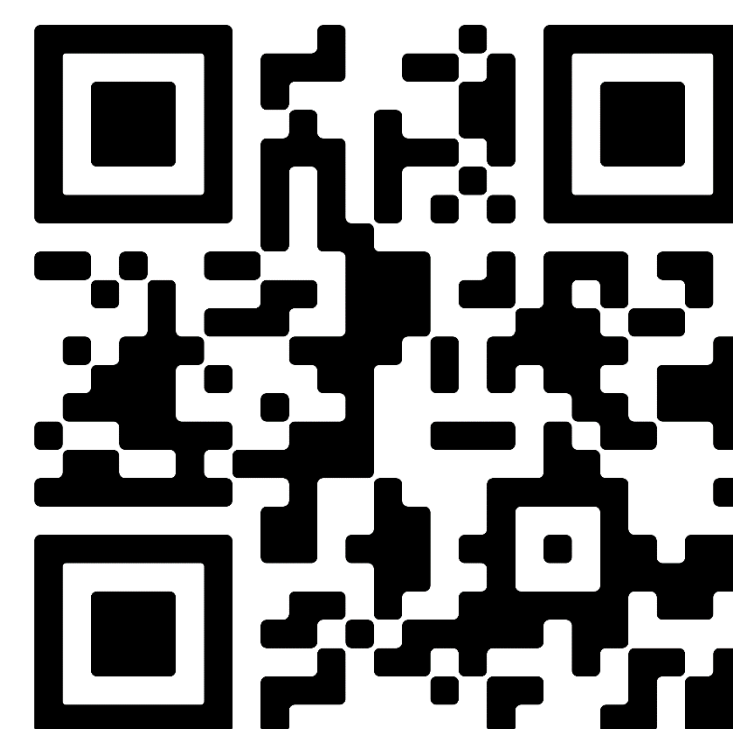
Biomarker: Imaging integrated use of in vitro, pre-clinical, & clinical imaging methods

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

Scan to Learn More





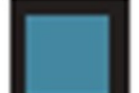


D3 is a collaboration between Johns Hopkins University and University of Maryland

-  Service at Johns Hopkins
-  Services at University of Maryland





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)
-  GMP-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)