# Partnering with Pfizer Worldwide R&D





## Worldwide R&D

#### **Our Partnering Philosophy**

Significant innovations with breakthrough impact for patients may be achieved by bringing together the best ideas and minds to turn great science into new medicine. The search for innovative ideas leads to forging partnerships with clear vision, open communication, and a strong collaborative desire to develop outcomes that would not be possible in isolation. Each partnership is unique, building on the strength of the parties working together to leverage significant disease expertise, development capabilities, and the drive to transcend obstacles and deliver solutions.

#### Worldwide R&D process

External Science & Innovation (ES&I) – our externally-focused scientific team of high-profile PhDs/MDs, embedded within our research groups – identifies late-breaking science that forms the basis of innovative therapies and drives collaborations that are aimed at delivering value to Pfizer, our partners and patients. ES&I works closely with Pfizer's Business Development, Venture Investment groups and other business lines to form an effective partnering team with a diverse blend of research, clinical and business expertise.

#### **Partnership Models**

What are you looking for in a partnership? Pfizer engages in flexible partnership models that includes research collaborations, venture capital investments, academic alliances for drug development, early stage seed funding, establishing incubators, licensing, spinning out of companies.

Start a conversation with us, let's learn about each other and discover synergies, goals, needs and capabilities. There are patients who are waiting, and together, we might deliver on the promise of better health and longer lives.



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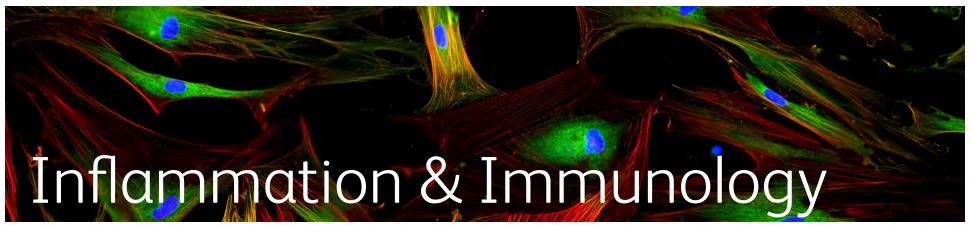
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For more details, please visit us on line at: www.pfizer.com/wrdpartnering

# Innovative Partnering Platforms



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The Inflammation & Immunology Research Unit, led by Michael Vincent, Chief Scientific Officer, is focused on discovering, evolving and developing the next generation of therapies for immune-mediated diseases. Pfizer is interested in entering into strategic relationships with innovative collaborators to develop increasingly novel and differentiated therapies in Rheumatology, Gastroenterology and Medical Dermatology.

#### We are interested in establishing alliances to develop and access:

- Rheumatoid Arthritis
- Systemic Lupus Erythematosus
- Inflammatory Bowel Disease
- Nonalcoholic steatohepatitis (NASH)
- Atopic Dermatitis
- Other indications with high unmet need that are mechanistically related to those above

#### Specific areas of interest include:

- Cytokines and their signaling pathways
- Adaptive Immunity, Lymphocyte biology including Th17 lymphocytes
- Regulatory cells and Tolerance induction

- Host-microbial interactions and microbiome with an interest in epithelial barrier
- Innate Immunity and Innate Lymphoid Cell biology
- Oxidative stress modulators
- Anti-fibrotics
- Technology platforms and products to help understand patient segmentation in the disease areas of interest and develop precision medicine strategies for innovative portfolio products
- Technology platforms and products that allow for greater tissue and cell specific delivery
  - Not actively seeking partnering opportunities in:
  - TNF*a*, IL-1β targeting biologics
  - B cell depleting biologics
  - Corticosteroids

#### External Science & Innovation Contact: Arpita Maiti (arpita.maiti@pfizer.com); Javier Cote-Sierra (javier.cote-sierra@pfizer.com)

## Internal Medicine

### Metabolic Diseases

Metabolic Diseases, specifically Type 2 diabetes (T2D), NAFLD/NASH and obesity, are major health problems that have reached epidemic proportions worldwide. Importantly, CVD and T2D impose large economic burdens on the individual patient and on national healthcare systems and economies.

#### We are interested in establishing alliances to develop and access:

- Metabolic therapies for non-alcoholic, fatty liver disease (NAFLD) and Nonalcoholic steatohepatitis (NASH)
- Dyslipidemia Obesity and Eating Disorders
- Diabetes and related co-morbidities

#### Specific areas of interest include:

- Decreasing hepatic lipid content and inflammation and the development of liver fibrosis in patients with NASH/NAFLD
- Identifying and qualifying novel biomarkers non-invasive biomarkers for NASH
- Improving cardiac performance via metabolic reprogramming of more efficient energetics
- Novel therapies that reduce hyperinsulinemia and hyperglycemia. Addressing obesity and eating disorders to induce and sustain weight loss
- Brain signals that regulate energy homeostasis and metabolism
- Centrally-acting anorectics

#### Not actively seeking partnering opportunities in:

- Anti-thrombotics
- Anti-arrhythmics
- Stable Angina treatments
- Cardiovascular Disease

#### External Science & Innovation Contact: Lauren Shearman (lauren.shearman@pfizer.com)

## Internal Medicine

### Neurodegenerative Diseases

Pfizer has made significant investments in discovering and acquiring innovative products for Alzheimer's and Parkinson's disease and we are focusing our efforts in these two areas to provide healthcare solutions with novel products for both the treatment of unmet symptomatic needs and transformative disease modifying therapeutics.

#### We are interested in establishing alliances to develop and access:

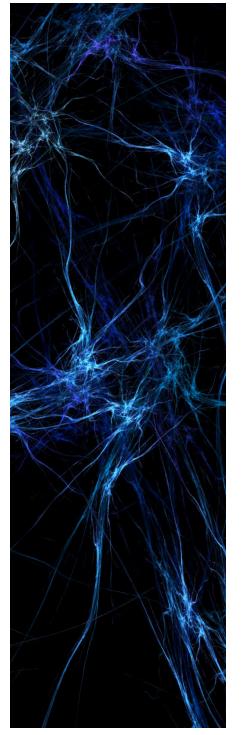
Alzheimer's Disease (AD) & Parkinson's Disease (PD) (more)

#### Other areas of focus:

- Agents modulating chronic neuroinflammation with evidence of impact on AD or PD pathophysiology
- Cerebral amyloid angiopathy and vascular impairment associated with neurodegeneration
- Imaging agents (e.g., tau, synuclein, neurotransmitters, neuroinflammatory markers and gliosis)
- Phase 2-3 Neuroscience or Pain product opportunities with unique and transformative health care impact

#### **Enabling Technologies:**

- Mechanistic and clinical biomarker innovations for AD and PD
- Technology platforms for patient data and precision medicine support
- Liquid biomarkers coupled with phenotype, genotype and drug history, to predict responders, monitor disease, and to identify prodromal patients
- Access to consortia and data related to natural history of neurodegenerative diseases and tools with which to analyze these databases and relationships between early endpoints and long-term outcomes.



### Internal Medicine Neurodegenerative Diseases

- Alzheimer's Disease (AD) & Parkinson's Disease (PD)
  - Disease modifying approaches and therapeutics
  - Symptomatic treatments and approaches for AD and PD
  - Specific CNS behavioral and non-motor functional impairments and mechanisms targeting impaired cognition/executive function and reward/motivation in these diseases. Clinical unmet need for the treatment of systemic dysfunctions related to peripheral nervous system disorders in AD and PD.
  - Strategic partnerships at all levels, including molecular, pharmacological, biological, biomarker and clinical trial innovations.



Our core areas of interest include: Tumor Cell Biology; Bioconjugates Discovery and Development; Precision Medicine; Integrative Biology and Biochemistry; and Immuno-Oncology. In Tumor Cell Biology, we are focused on oncogenic drivers, immuno-oncology metabolism, and epigenetics. Our Bioconjugates group efforts emphasize our expertise in antibody-drug conjugates (ADCs), bispecific mAbs, and targeted nanoparticles. Precision Medicine represents an integrated cluster of technology platforms and translational science configured to enable patient-tailored, hypothesis-driven experimental medicine approaches. Our Integrative Biology and Biochemistry team supports novel target identification and validation through functional genomics, proteomics, and other "omic" approaches. Our immuno-oncology group focuses on adaptive and innate immunomodulation as well as T cell redirected therapies including CD3 bispecfics and CAR-T.

#### We are interested in establishing alliances to develop and access:

- Lung, colorectal, breast, prostate, ovarian, renal, pancreatic and hematologic cancers
- Cancers prevalent in Asia (e.g., gastric cancer, hepatocellular carcinoma)

#### Specific areas of interest include:

- Oncogenic signaling mechanisms
- Tumor immune modulating metabolism targets
- Epigenetics
- Small molecule immuno modulators
- Directed tumor cell killing via immune-based mechanisms

(more)

### Immuno-Oncology

We are advancing our leadership in this cancer immunotherapy by partnering to develop cutting edge science beyond the current mainstream immune checkpoints, e.g., CAR-T, CD3 bispecifics, vaccinia, and small molecules.

### We are interested in establishing alliances to develop and access:

- Novel Targets for Overcoming Tumorinduced Immune Resistance
- Cell-based Therapies
- Platform Technologies

(more)

#### External Science & Innovation Contact: Denis Patrick (denis.patrick@pfizer.com)



# Oncology

#### Specific areas of interest include:

- Precision medicine
- Functional genomics
- Liquid biopsy technologies
- Technologies that deliver drugs asymmetrically to tumor tissues
- Targeted nanoparticle technologies and assets
- Novel cell therapies
- New mechanisms of action for immunotherpay



# Immuno-Oncology

#### Novel Targets for Overcoming Tumor-induced Immune Resistance

- Targets that promote immune response whether alone or in combination with checkpoint inhibitors
- Targets that provide innate immune support/activation
- Targets that reduce immune suppression

#### Cell-based Therapies

- CAR-T, TCR, NK, and other hybrid targeting modalities with a focus on allogeneic approaches

#### Platform Technologies

- Mechanisms, biomarkers, and screening approaches to identify and accelerate the most promising combination therapies
- New modalities to induce immune responses: Bi-specific mAbs, nanoparticles, oncolytic viruses, tumor vaccines, chimeric antigen receptors (CARs), or novel T cell receptors (TCRs)
- Identification of new immune modulating targets
- Monitoring of immune-supporting and immune-suppressing biomarkers within the tumor as well as of the anti-tumor immune responses
- Novel animal models that accurately recapitulate human tumor-immune system interactions
- Integrated High Content Biomarker Platforms for predicting outcomes with oncology and immuno-oncology agents and developing mechanism-based, biomarker-driven treatments.
- Translational platforms for oncology and immune-oncology, including 3D tumor cell or organoid constructs with mixed cell populations and in vivo models that recapitulate the human tumor microenvironment and immune system.



Pfizer is adopting an innovative and collaborative approach to the development of new medicines for patients with rare diseases. We have a track record of creating innovative strategic partnerships with academic institutions, patient advocacy groups, and commercial enterprises to accelerate the development of novel therapeutics across the entire spectrum of rare diseases. We are looking to benefit from recent scientific advances linking diseases to specific genetic defects. As 70% of rare diseases are monogenic in origin, we believe this is an area where scientific knowledge is enabling significant advances in drug development. Our expertise in large molecule therapeutics, as well as small molecule protein chaperones and transcriptional modulators, has resulted in a broad pipeline of potentially transformative medicines across multiple disease areas.

#### We are interested in establishing alliances to develop and access:

- Hematology (non-malignant) (more)
  - Hemophilia
  - Other rare hematologic non-malignant indications
    - Sickle cell anemia & beta-thalassemia, with focus on disease modifying therapies
    - Hemostasis (systemic and topical)
    - Opportunistic approaches in the field of hematology that promise well differentiated novel medicines
- Neuromuscular Diseases
  - Duchene/Becker muscular dystrophy
  - Friedreich's ataxia
  - Amyotrophic Lateral Sclerosis (ALS)
- Disease modifying approaches for other diseases such as Huntington's disease and other ataxias and rare childhood seizure disorders

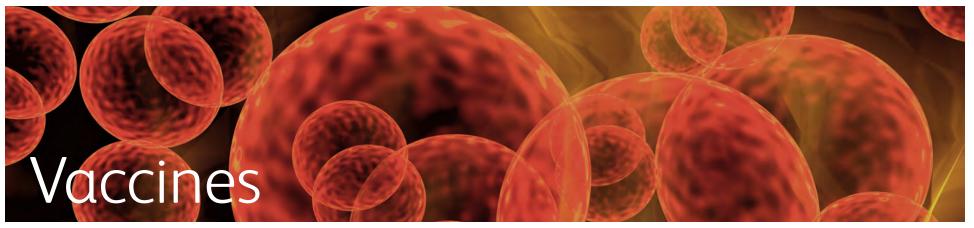
#### Not actively seeking partnering opportunities in:

- Undifferentiated approaches in well-served markets
- Medical devices
- Diagnostic tests (in absence of a therapeutic approach



## Rare Disease

- Hematology (non-malignant)
  - Hemophilia
  - Coagulation factors with extended duration of activity and/or improved delivery
  - Oral agents to treat hemophilia
  - Immune tolerance
  - Novel approaches to treat hemophilia patients



Our vision is to become a recognized leader in the discovery and development of innovative prophylactic and therapeutic vaccines for unmet medical needs throughout all stages of life and for all geographies and markets. We focus on Prevention of viral and bacterial infections in infants, children, adolescents and older adults; hospital acquired infections; and active immune oncology (cancer vaccine) targets,

#### We are interested in establishing alliances to develop and access:

- Vaccines for the prevention and/or treatment of infectious diseases
- Vaccines for the prevention and/or treatment of non-infectious diseases with special emphasis on cancer vaccines through the active elicitation of disease-modifying immune responses

#### Specific areas of interest include:

- Adjuvants
- Novel immune system enhancers to bolster the immune system of an older population
- Novel in vitro systems for assessment of vaccine immunogenicity
- Novel animal models for assessment of vaccine effectiveness
- Novel immunomodulators of the adaptive immune response
- Novel vaccine target antigen identification systems
- Novel vaccine delivery platforms
- Novel vaccine platforms with game-changing potential

#### Not actively seeking partnering opportunities in:

 Novel vaccines in disease areas for which effective vaccines are already available/licensed (with the exception of novel influenza virus vaccines)

#### External Science & Innovation Contact: Barbara Sosnowski (barbara.sosnowski@pfizer.com)



*Pfizer's Drug Safety R&D group develops and applies the skills, experience and scientific tools necessary for safety assessment and risk management of targets and compounds across the research, development and commercial phases of drug development. We seek to enhance our capabilities for target safety assessment, selection of safer compounds, toxicity risk management and translation of preclinical models.* 

#### We are interested in establishing alliances to develop and access:

- Mechanisms, translatable and monitorable biomarkers, and probabilistic screening approaches related to target organ toxicity (more)
- Computational toxicology (more)
- Animal models, biomarkers and screening approaches for preclinical immuno-oncology investigation, supporting mono- and combination-therapy approaches (interpretation and translatability) (more)
- Biotherapeutics-related analytical technologies (more)
- Access to and utilization of normal and diseased human biospecimens
- Deeper knowledge of targets and pathways and novel technologies and increased throughput for target localization studies
- Advancing Regulatory Science (more)



# Drug Safety

- Mechanisms, translatable and monitorable biomarkers, and probabilistic screening approaches related to target organ toxicity, such as:
  - Cardiovascular safety, vascular injury
  - CNS biomarkers including peripheral neuropathy
  - Liver injury in particular immune-mediated DILI and transporters
  - Immunostimulation, including hypersensitivity, autoimmunity, cytokine release
  - Nephrotoxicity glomerular and tubular

#### Computational toxicology

- Novel data insights (Big Data)
- Predictive computational models and mechanistic understanding
- Genetic and proteomic approaches for patient stratification, human translation of toxicology findings or monitorable biomarkers and disease pathogenesis
- Animal models, biomarkers and screening approaches for preclinical immuno-oncology investigation, supporting mono- and combination-therapy approaches (interpretation and translatability)
  - Immune system components and responses comparability between preclinical species and human
- Biotherapeutics-related analytical technologies
  - Immunogenicity and other safety-relevant assays
  - Assays to assess safety of CAR-T and gene therapy for humans
- Advancing Regulatory Science
  - Systems pharmacology approaches for prediction of adverse events



Pfizer is committed to leading in this space by bringing together the foremost expertise in vector design and development with in-house knowledge of disease biology and manufacturing capabilities. Our current collaboration with Spark Therapeutics Inc. on Hemophilia B, with Sangamo Therapeutics Inc. on Hemophilia A and our acquisition of Bamboo Therapeutics, form the basis upon which we intend to continue building our gene therapy programs and capabilities. We see gene therapy as a key pillar of our Rare Disease strategy. In addition we are interested in the application of gene therapy to select central nervous system (CNS) and heart diseases. We are also seeking promoter technologies, as well as industry-leading vector analytics and immune surveillance approaches, and in-vivo gene editing technologies.

#### We are interested in partnering to develop and access:

- Novel Targets in key areas of interest
  - Parkinson's Disease
  - Huntington's Disease
  - Spinal Muscular Atrophy
  - Muscular Dystrophy
  - Alzheimer's Disease
  - Sickle Cell Disease

- Novel AAV vectors with strong tissue-specific tropism (CNS, liver, and heart) with favorable transduction/expression
- Promoter or gene regulation technology to ensure regulated and sustained tissue-specific gene expression
- Vector analytics to identify viruses with superior bioactivity
- AAV immunology expertise to test/challenge existing hypotheses and develop more robust gene therapy products

# Genome Sciences & Technologies

Genome Sciences & Technologies has two primary objectives. One is to set the investment strategy for platform technologies across Pfizer R&D. The other is to support Pfizer R&D as a fully integrated genomics partner line comprising Human Genetics (including Functional Genomics), Computational Biomedicine & Target Validation, Diagnostics as well as Clinical Genetics & Biospecimen Scientific Services groups.

#### We are interested in establishing alliances to develop and access:

- R&D Platform Technology strategies, e.g., in drug design and delivery, translational genomics, therapeutic modalities and precision medicine
- Highly characterized patient cohorts, including extreme phenotypes, for genetic studies in diseases of interest to Pfizer
- Population-based Biobanks and high-quality, longitudinal genotype phenotype data sets
- Human Genetics & Functional Genomics technologies, e.g., CRISPR-based screening approaches, omics profiling and analytics
- Breakthrough diagnostic technologies, including blood-based diagnostics in oncology and near-patient diagnostics testing
- Advanced Analytic technologies, capabilities and data environments, e.g., machine learning, deep learning & other approaches for analysis of EHR & multi-dimensional life science data sets as well as add-on technologies to complement analyses & interpretation



These lines cover core scientific disciplines enabling delivery of medicines and vaccines from idea to loss of exclusivity and include industry-leading capabilities with more than 2,700 colleagues in ten major sites working on every project within Pfizer's portfolio.

### Biologics Product & Process Development (more)

Next generation of microbial and mammalian cell protein production systems



Transformational technologies to design, construct, and optimize biotherapeutics



Computational methods to integrate, manage, visualize, and mine largescale compound-centric datasets from published literature and patents



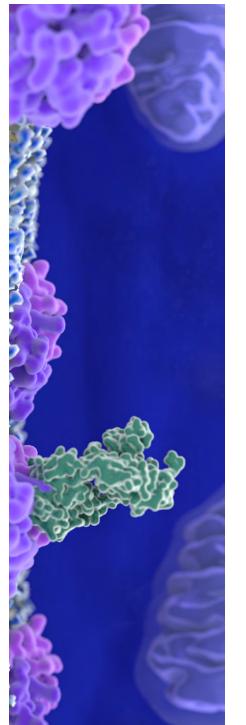
Translational research – large & small molecule efforts



Novel flow chemistry approaches that enable mg to kg scale



Computational Product and Process Design



### Medicinal Sciences Biologics Product & Process Development

- Microbial and mammalian cell protein production systems
- Process and manufacturing technologies
- Cell (T-cell) and gene therapy manufacturing technologies
- "cell-scale" analytical technologies for phenotype
- Systems and Synthetic Biology
  - Technologies to design and influence host cell performance and product quality
  - Novel expression systems with alternative posttranslational modifications (e.g., glycosylation)
  - Automated methods for mammalian cell line screening, selection and scale up
  - Next generation cell culture process technologies and purification process technologies, including harvesting (smart polymer automation)
  - High throughput analytics for product quality attributes
  - Advanced analytics for glycoconjugates and antibody drug conjugates (ADC)
  - Flexible and adaptive manufacturing technologies for biotherapeutics
- Technologies for improved, targeted viral vector transduction of primary T-cells
- Alternative, large-scale, closed, cell electroporation technologies

- Large-scale, targeted nanoparticle delivery of DNA/mRNA into primary T-cells
- Technologies for purification of specific cell subpopulations; cell concentration/buffer-exchange technologies
- Control of T-cell proliferation and differentiation; memory cell replenishment

We are interested to ensure commercial and clinical differentiation of products by accessing leading drug delivery technologies.

#### Specific areas of interest include:

- Tissue specific delivery; nanoparticle technology
- Alternative routes of delivery (transdermal, transmucosal)
- Analytics (biophysics) to predict stability and ease of development
- Advanced formulations (high dose delivery, convenient dose administration)
- Innovative injectors including large volume bolus injectors, and compliance and adherence supporting systems



### Medicinal Sciences Biotherapeutics Discovery

- Transformational technologies to design, construct, and optimize biotherapeutics
  - Informed protein design optimizes molecular properties resulting in superior efficacy, pharmacokinetics, pharmacodynamics, safety, manufacturability and differentions
- Bioconjugation technologies
  - Novel approaches that enhance antibody function or improve site-specific bioconjugation
- Combinatorial biologics such as bi-specific and multi-functional platforms with promising biophysical and manufacturing properties
- Structure-based and computational design of therapeutics
  - Novel technologies to rationally design antibody, protein and peptide therapeutics that display superior pharmaceutical properties (including selectivity, half-life extension, stability, formulatability)
- Technologies that enhance multi-transmembrane protein target expression/presentation for antibody generation and screening
- Technologies and patient sample access for antibody discovery from human antibody responses
- Targeted delivery technologies that address/overcome cell membrane penetration, cross blood brain barrier
- Technologies that can significantly enhance general protein expression, purification, stability for discovery
- Integrated service providers to support early discovery activities for development of therapeutics
- Broadly applicable platforms to enhance speed/quality of antibody generation
- Novel biologics, combination therapies, and "biobetters" that fit Pfizer strategies



### Medicinal Sciences Medicinal Chemistry

- Computational methods to integrate, manage, visualize, and mine large-scale compound-centric datasets from published literature and patents
- Technology to expand NCE target space orally bioavailable and cell penetrable peptides, and non-Ro5 compounds
- Natural product synthetic biology and screening technologies
- Ion channel modulator design and screening technologies
- Membrane protein structural biology technologies and capabilities, including ion channels, GPCRs and solute carrier proteins
- Computational methods for quantitative affinity prediction and molecular dynamics simulation
- New high efficiency synthetic transformations and novel flow chemistry approaches
- Systems/chemical biology technologies enabling mechanism determination for phenotypic screening hits

- Bioinformatic approaches to define target selectivity
- CH activation chemistry
- Novel synthetic methodology to access small conformationally constrained multifunctional templates
- Novel strategies for enhancing permeability of poorly absorbed molecules
- Novel fragment or compound collections validated for protein-protein interaction targets
- New chemistry to develop disease imaging agents (e.g., plaques/AD, beta cells/T2D, angiogenesis/cancer)
- Novel methodology and capabilities to enable 18F chemistry
- Biophysical techniques to enable rapid state dependent ion channel screening
- Novel receptor mediated and transporter mediated tissue targeting strategies
- High content and in silico approaches to predict small molecule toxicity

# Medicine Design

- Translational research large and small molecule efforts
  - Translational modeling and simulation approaches, systems pharmacology/PK-PD; deep knowledge of targets/pathways; increased confidence in target drug selection
- Quantitative Bioanalytics, Biomarkers, Biomeasures, and Immunogenicity Assays
  - Science and applications involving differential ion mobility
  - MALDI, acoustic or "non-traditional" ultra-rapid ionization and sample introduction technologies for mass spec screening
  - Novel LC-MS/MS large molecule bioanalysis and automation techniques
  - Stable isotope labelled pulse chase studies with LC-MS/MS to measure target turnover
  - Novel bioanalytical and cellular imaging techniques for biomarkers/biomeasures
  - Development of a universal platform for cell-based neutralizing antibody assays
  - Biocomparability: identification of critical attributes influencing PK and disposition
  - Targeted and untargeted metabolomics and fluxomics
- Disposition and delivery of therapies large and small molecule efforts
  - Novel commercially viable delivery technologies (oral and non-oral, including topical)
  - Predictive technologies targeting oral absorption and disposition of peptides
  - Biodistribution of nanoparticles and large molecules at whole organ and cellular level

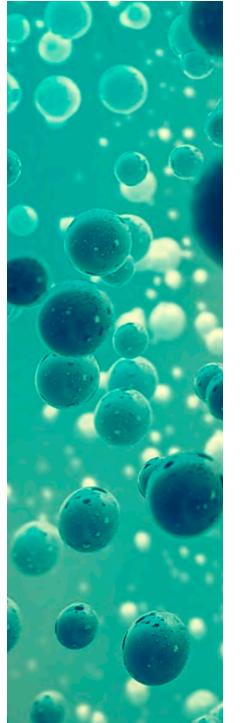
#### Targeting, prediction and modeling of transporter-mediated disposition and DDIs – small molecules

- Quantitation and scaling of transporters for input into physiological PK models of tissue penetration and clearance including biliary clearance
- Determination of intracellular unbound concentrations of transported drugs
- Novel approaches to achieving selective tissue distribution including nanoparticles

### Medicinal Sciences Medicinal Synthesis Technology

#### We are interested in establishing alliances to develop and access:

- Novel flow chemistry approaches that enable mg to kg scale
- Efficient scale-up (kg) capabilities for photo redox chemistry
- Novel chemical transformations via biocatalysis
- Novel synthetic methodologies for late stage diversification
- DNA-compatible synthetic protocols that expand currently available methodology for DNA-encoded libraries (DEL)
- DNA backbone modifications that expand synthetic transformations compatible with preparation of DEL
- Monomers and building blocks in drug-like property space
- High-throughput optimization capabilities for synthetic transformations and biocatalysis
- Innovative capabilities for parallel medicinal chemistry
- New synthetic technologies that can accelerate the delivery of API



### Medicinal Sciences Small Molecule Product & Process Development

- Computational Product and Process Design (CPPD)

   To complement and advance our experimentation and manufacturing processes with computational tools, including translating drug molecular structures to material properties in silico. Some of the areas of interest include in silico design & screening of synthetic pathways and structure-based stability prediction.
- Materials Sciences and Particle Engineering Development of molecular structure-based particle design and engineering tools that allow for the prediction and manipulation of crystal form/morphology, solid-state stability and material properties.
- Portable, Continuous, Miniature and Modular Development and Manufacturing Equipment – Design and development of fit-for-purpose, small footprint, plug-and-play (modular) processing platforms, for drug product and API that allow the same equipment to be used for development and commercial manufacturing. Desired state is for processing modules to be capable of manufacturing multiple products at a wide range of scales and enable significant reduction in scale-up and technology transfer efforts.
- Innovative Chemical Synthesis Development of new platform syntheses that include sustainable/"green" chemical technologies and innovative chemical transformations. Partnerships in the areas of replacement of endangered metal catalysts and general methods for catalytic preparation of chiral amines are desired.

- Drug Delivery Technologies Advanced drug delivery technologies to enable differentiated therapies and the next generation of precision medicine. Specific areas of interest include:
  - Novel parenteral solubilization and delivery approaches
  - Membrane permeability-enhancing drug delivery platforms
  - Differentiated pediatric dosage forms (ideally solidsbased) that mask, neutralize or improve taste without affecting the pharmacokinetics for oral immediaterelease products
- Advanced Analytical Technologies Innovative analytical platforms to enable real-time process understanding and/or control via on-line or at-line technology for Drug Product and API. Specific areas of interest include:
  - Process Analytical Technologies (PAT) and sensor technology for advanced process control
  - Microfluidic sample handling platforms compatible with continuous manufacturing processes
  - Miniaturized, robust separation sciences platforms
  - 3-D mapping/imaging of drug products

## **Precision Medicine**

We are focused on Precision Medicine as an approach to discovering and developing medicines and vaccines that deliver superior outcomes for patients, by integrating clinical and molecular information to better understand the biological basis of disease and the molecular pharmacology of our drugs. This effort leads to better selection of disease targets, more tailored drugs and identification of patient populations that demonstrate improved clinical outcomes.

#### We are interested in establishing alliances to develop and access:

- Patient cohorts with high quality longitudinal clinical (e.g. electronic medical record), molecular and other phenotypic data preferably paired with the availability of broadly/appropriately consented biobanked biospecimens (e.g. whole blood serum/plasma, PBMCs, stool, etc.), and with the potential for patient recall
- Systems Biology/Pharmacology (more)
- Breakthrough diagnostic technologies that are highly quantitative, require minimal specimen/tissue, offer quick turnaround time and can be multiplexed. (more)
- In vivo imaging technologies (including MRI, PET, CT, optical imaging technologies, imaging agents, genetically encoded tags, etc.) (more)
- Biospecimen Analysis (more)
- Physiological Biomarkers (more)
- iPS cell resources and technologies to generate iPS cells that may be used to enable Precision Medicine strategies (more)
- Biospecimen collection/stabilization technologies (more)
- Remote Patient monitoring technologies (more)
- Advanced computational biology approaches/platforms (more)

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## Precision Medicine

- Systems Biology/Pharmacology
  - Databases with high quality treatment and disease outcomes associated with genetic, as well as molecular (metabolomic, proteomic, transcriptomic, epigenetic, clinical chemistry markers) or functional measures in particular imaging data
  - Databases of searchable eQTLs, pQTLs across tissues
  - Disease biology guided combination therapy design platforms
  - Systems biology approaches and proven in silico tools to evaluate pharmacological perturbation and elucidate mechanisms of in vivo toxicity
  - Mining of data for correlation and understanding of causality
- Breakthrough diagnostic technologies that are highly quantitative, require minimal specimen/ tissue, offer quick turnaround time and can be multiplexed. This will include but not limited to:
  - Near-patient Point-of-Care technologies
  - Next Generation Sequencing technologies
  - Circulating cells
  - Circulating and urinary cell-free nucleic acids
  - Antigen receptor sequencing
  - Microbiome, including virome characterization
- In vivo imaging technologies (including MRI, PET, CT, optical imaging technologies, imaging agents, genetically encoded tags, etc.) with particular interest in
  - Imaging agents for small and large molecule compound distribution studies
  - Imaging agents monitoring physiology mechanisms and disease
  - Analytical tools and technologies

## Precision Medicine

#### Biospecimen Analysis

- Circulating tumor cell and cell free Nucleic Acid quantification and analysis
- High dimensional single cell analysis platforms Automated IHC for tissue analysis (cancer, safety)
- Advanced ADME-related genotyping
- 3D cell models for safety and efficacy assessment that ideally incorporate genetic diversity

#### Physiological Biomarkers

- Technologies adding precision to pain management and treatment in pre-clinical clinical studies
- EEG-based biomarker for assessment of central pharmacology
- iPS cell resources and technologies to generate iPS cells that may be used to enable Precision Medicine strategies
  - Validated cell differentiation protocols
  - iPS cells derived from sub populations with specific genotypic/phenotypic data
  - Technology to create iPS cells in a rapid and reproducible fashion without insertional approaches
- Biospecimen collection/stabilization technologies
  - Novel sample collection approaches that allow frequent (at home) sample collection with appropriate stabilization
- Remote Patient monitoring technologies
  - Novel actigraphy and other home monitoring systems that allow frequent at home monitoring of relevant physiological states/biomarkers
- Advanced computational biology approaches/platforms:
  - integration of high-dimensional data across various platforms in combination with classical clinical readouts for the predictive modeling of patient response/disease progression

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