# POSITIONING YOURSELF FOR A CAREER IN PHARMACEUTICAL CONSULTANCY

**Michael Shiue, Ph.D.**

**President, iNetX Corporation**

dr.shiue@gmail.com

**(626)806-9030**

# MY CAREER PATH

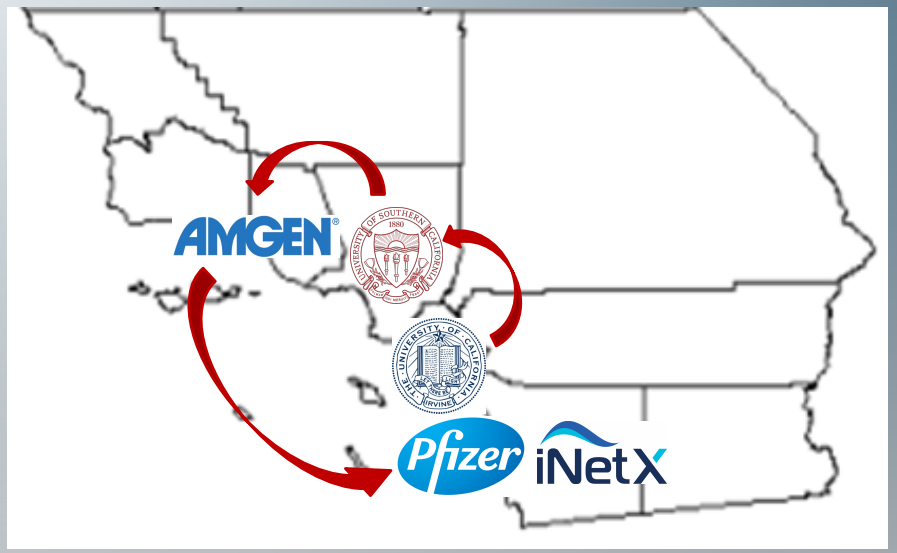
**1993** **University of California, Irvine**
B.S. Biological Sciences, Minor in Japanese Language & Literature (started as a Chemistry major)
Once considered a career as a professional photographer (Photo Editor, New University)
(took 6 months off)

**2000** **University of Southern California**
Ph.D. Pharmaceutical Sciences

**2000** Scientist, **AMGEN Inc.**
Pharmacokinetics and Drug Metabolism
(4 months before Ph.D. thesis defense)

**2008** Senior Principal Scientist, **Pfizer Global R&D**
Pharmacokinetics, Dynamics, and Metabolism
(1 week before being laid off)

**2018** President, **iNetX Corporation**
(laid off before establishing company)



# MY BACKGROUNDS

Graduate Training: ocular ion, solute, and drug transport (ion channels and transporters)

Pharma/Biotech Industry Experience (20 years):

- Industry Expertise: pharmacokinetics and ADME (absorption, distribution, metabolism, and excretion)
- Therapeutic Areas: oncology, CNS, ophthalmology, rare diseases, metabolic disorders, etc.
- Drug Development Stages: early discovery, development, international regulatory filing, LOE support

# STAGES OF DRUG DISCOVERY & DEVELOPMENT

**DISCOVERY RESEARCH**

- CHEMISTRY, BIOCHEMISTRY, MOLECULAR BIOLOGY, PHARMACOLOGY, BIOINFORMATICS, PKDM, PHARM SCI.

**PRE-CLINICAL DEVELOPMENT**

- PKDM, PHARM SCI, TOXICOLOGY, PHARMACOLOGY

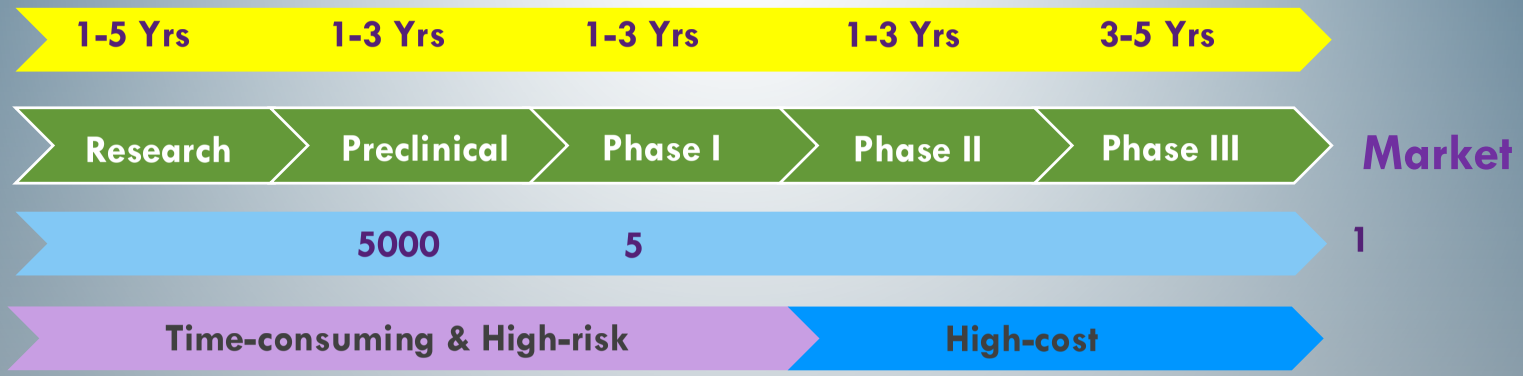
**CLINICAL DEVELOPMENT**

- CLINICAL, CLINICAL PHARMACOLOGY, BIOSTATISTICS, REGULATORY, PROJECT MANAGEMENT, PKDM, PHARM SCI

**POST MARKETING**

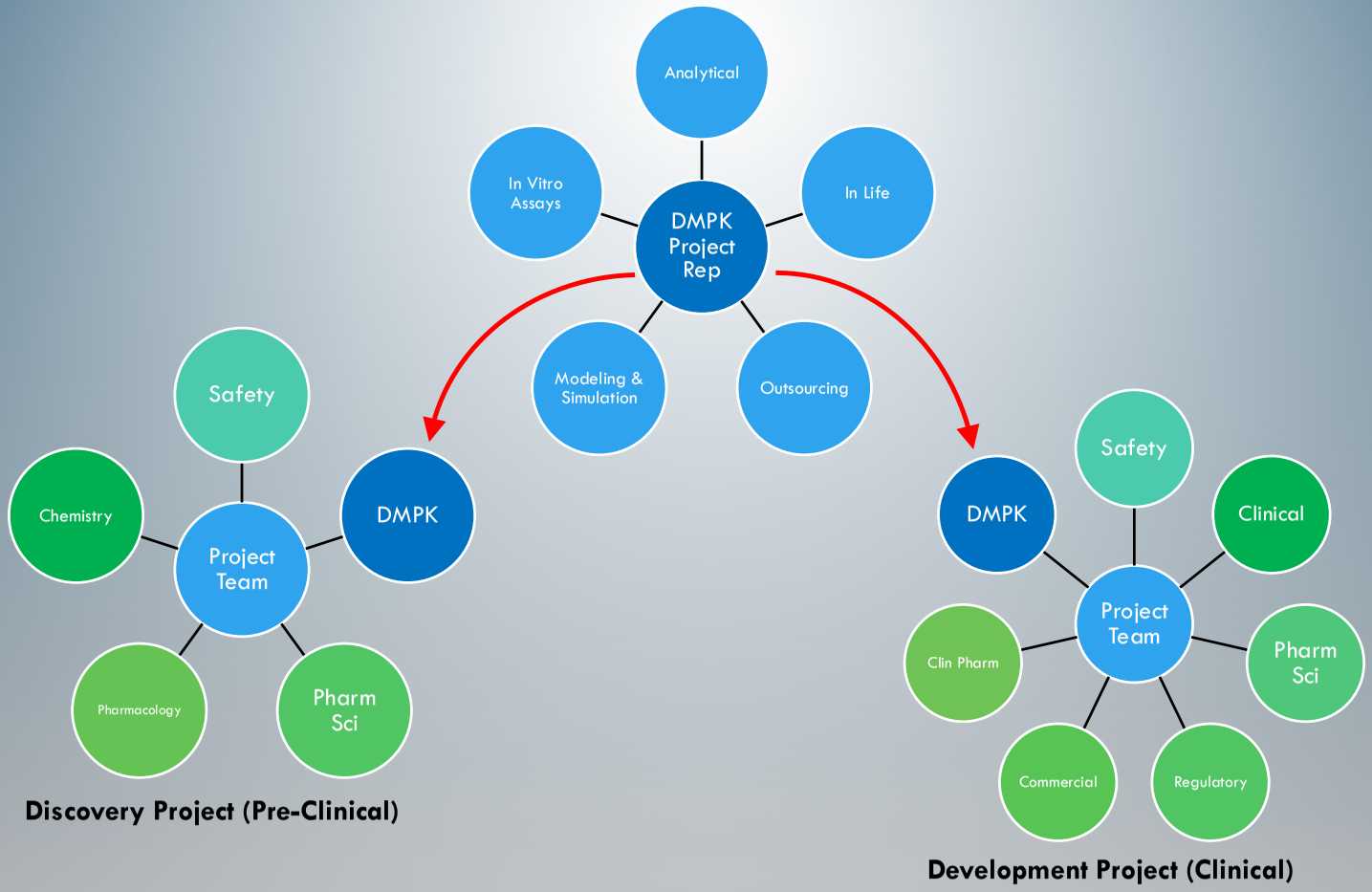
- COMMERCIAL, MANUFACTURING, QUALITY ASSURANCE, LEGAL, SALES, ETC.

# NEW DRUG DEVELOPMENT PROCESS




**12 Years, $359 million**

# DRUG DEVELOPMENT PARADIGM (MATRIX SYSTEM)



# MY QUESTIONS TO YOU

1. Why do you want to be a consultant?
2. If you were to become a consultant after completing your degree, what service would you provide?

# MY TYPICAL CLIENT PROFILE

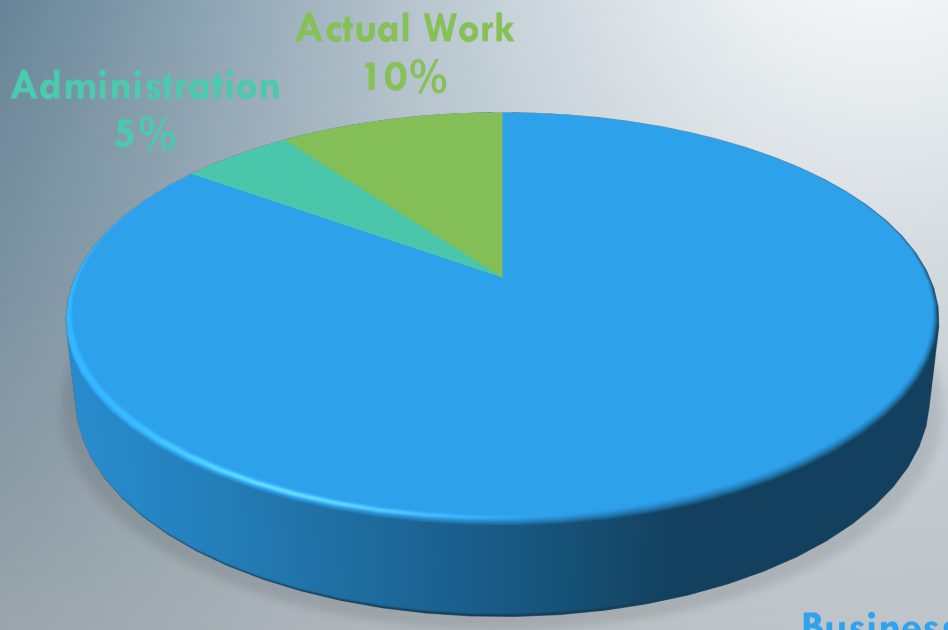
- Start-up to mid-size companies
- Limited drug development experience
- Pharmacology and/or clinical heavy
- Unfamiliar with ophthalmic development process
- Unfamiliar with nonclinical regulatory requirements
- Fluid timeline


**Consultant = Navigator**

# WHAT I DO FOR MY CLIENTS

- Provide guidance on nonclinical ophthalmic DMPK strategies and clinical trial-enabling data generation and evaluation.
- DMPK strategies for every stage of compound/device development
- Evaluation of nonclinical data to streamline development effort
- Exploratory and IND-enabling ocular PK and TK study design and execution
- Compose DMPK-related sections for international regulatory submissions
- Ocular therapeutics and technology in-/out-licensing due-diligence
- Feasibility assessment of alternative indications for drugs
- Staff training and establishing in-house ophthalmic development capabilities

# ACTIVITY TIME ALLOCATION




**Business Development Activities:**

**Maintaining established collaborations**
**Communication with past and idling clients**
**Networking events**
**Conferences**
**LinkedIn**
**Branding**

**Etc.**

# RECOMMENDATIONS FOR FUTURE CONSULTANTS

- Gain wide experience - scientific, process, as well as soft skills
- Know your industry
- Generate unique business proposition
- Your network is your lifeline
- Leverage your competitors
- Business development is a constant process
- Self discipline
- Be flexible