



# Agenda

- Overview of Phaseless Approach (5 Min.)
- Survey Outline (10 Min.)
- Company Updates (10 Min.)
- Next Steps (5 Min.)

# CLINICAL PHARMACOLOGY & THERAPEUTICS

VOLUME 61 NUMBER 3

MARCH 1997

## COMMENTARY

### Learning versus confirming in clinical drug development

Lewis B. Sheiner, MD *San Francisco, Calif.*

George Box' views scientific progress as consisting of, and requiring, alternating steps of induction and deduction: the former being learning from ex-

jects, what dose is tolerated (phase 1) and confirms that this dose has promise of efficacy in a selected group of patients (2A). The end of phase 2A is a



## U.S. Food and Drug Administration

[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

### Critical Path to New Development: Press Releases, Speeches, Testimony

#### Press Releases

[FDA and the Critical Path Institute Announce Predictive Safety Testing Consortium](#) (March 16, 2006)

[FDA Unveils Critical Path Opportunities List Outlining Blueprint To Modernizing Medical Product Development by 2010](#) (March 16, 2006)

[FDA Issues Advice to Make Earliest Stages Of Clinical Drug Development More Efficient](#) (January 12, 2006)

[FDA and Industry to Collaborate on Better Ways to Predict Liver Toxicity in Human Drug Trials - Part of FDA's Critical Path Initiative to Modernizing Drug Development](#) (November 2, 2005)

["Critical Path" Paper Calls for Academic Researchers, Product Developers, and Patient Groups To Work With FDA To Help Identify Opportunities to Modernize Tools for Speeding Approvable, Innovative Products To Improve Public Health](#) (March 16, 2004)

#### Speeches



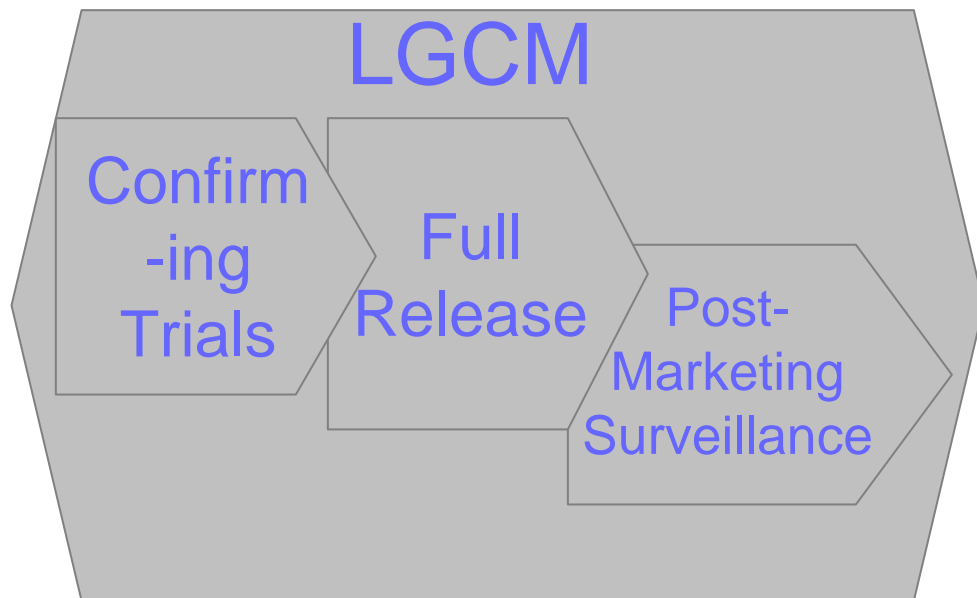
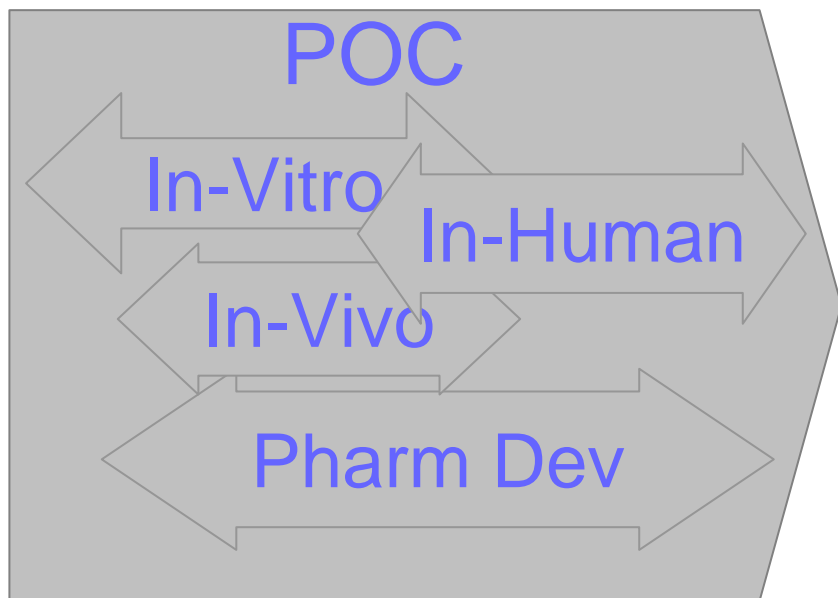
42<sup>nd</sup>  
Annual Meeting  
Philadelphia 2006

## New Approaches to Clinical Development: Novartis Experience

**John J. Orloff, M.D.**  
Vice President, Development  
Novartis Pharma AG



# Definition



No Phases = No Counting of Compounds




# Benefits - Professional

- Team Cohesion
- Minimal Bureaucracy
- Focus on science and scientific recognition (POC)
- Focus on architecture and standards (LGCM)
- Compensation tied to Market Success

# Phaseless R&D Survey (Outline)

- Organization
- Funding
- Mission – Focus
- Key POC Operational Features
  - Knowledge Acquisition
  - The Evidence Trail
  - End Point Selection

# Organization

~2,800  ~30 x

<b>Position Type</b>	<b>Count</b>
Administrative	5
Animal Care	3
Laboratory Animal Specialists	3
Biochemists	4
Biologists/Microbiologists	18
Chemists	5
Clinical Operations	1
Clinical Research	4
Drug Metabolism	4
Early Development API Analytic Research Fellows	11
Imaging Specialists	1
Information Technologists	3
Senior Investigators	3
Laboratory Operations	1
Medical Program Clinician	3
Medical Program Coordinator	4
Medicinal Chemistry (Structural)	7
Pharmacology	1
Research Associates	7
Toxicologists	2
Veterinary Scientists	1
<b>Grand Total</b>	<b>92</b>

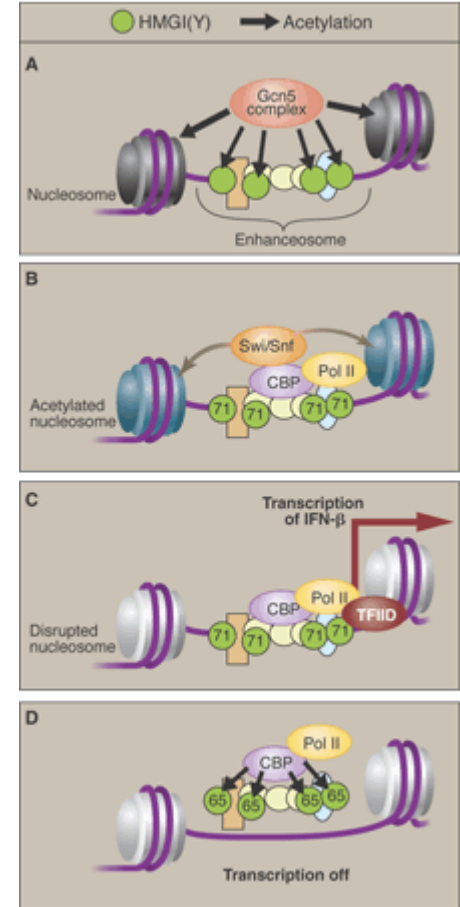
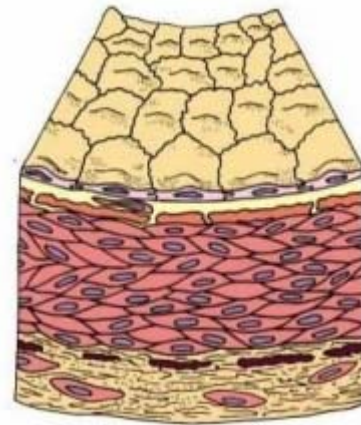
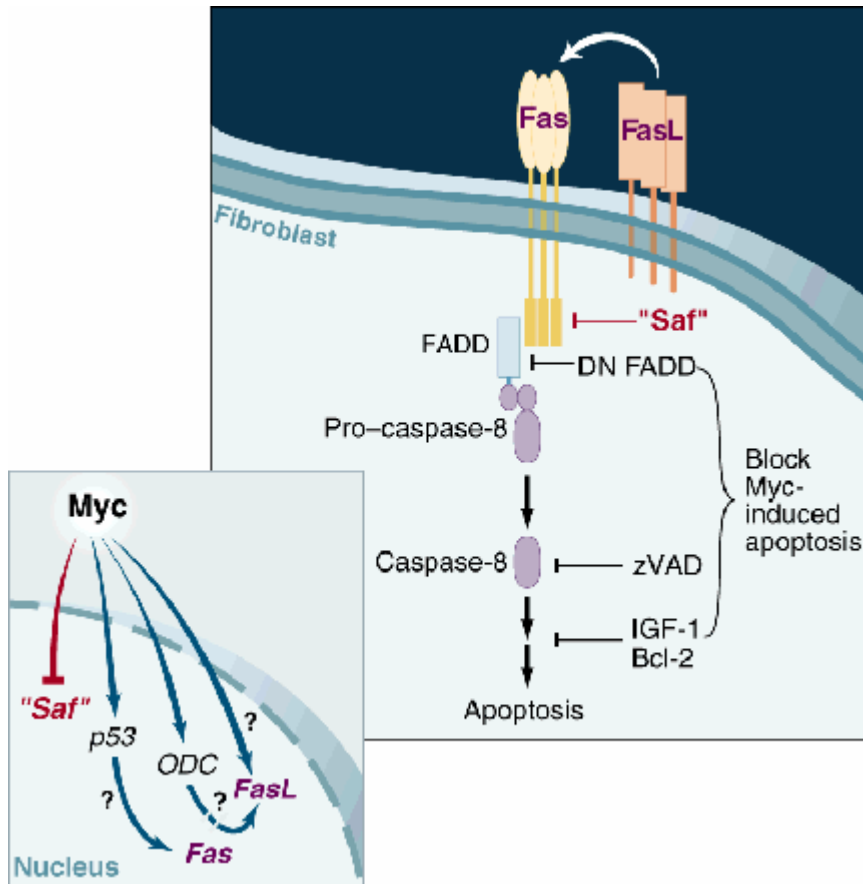
## POC

- Direct costs
- Clinical trials within POC
- Clinical trials in LMGCM
- Shared services

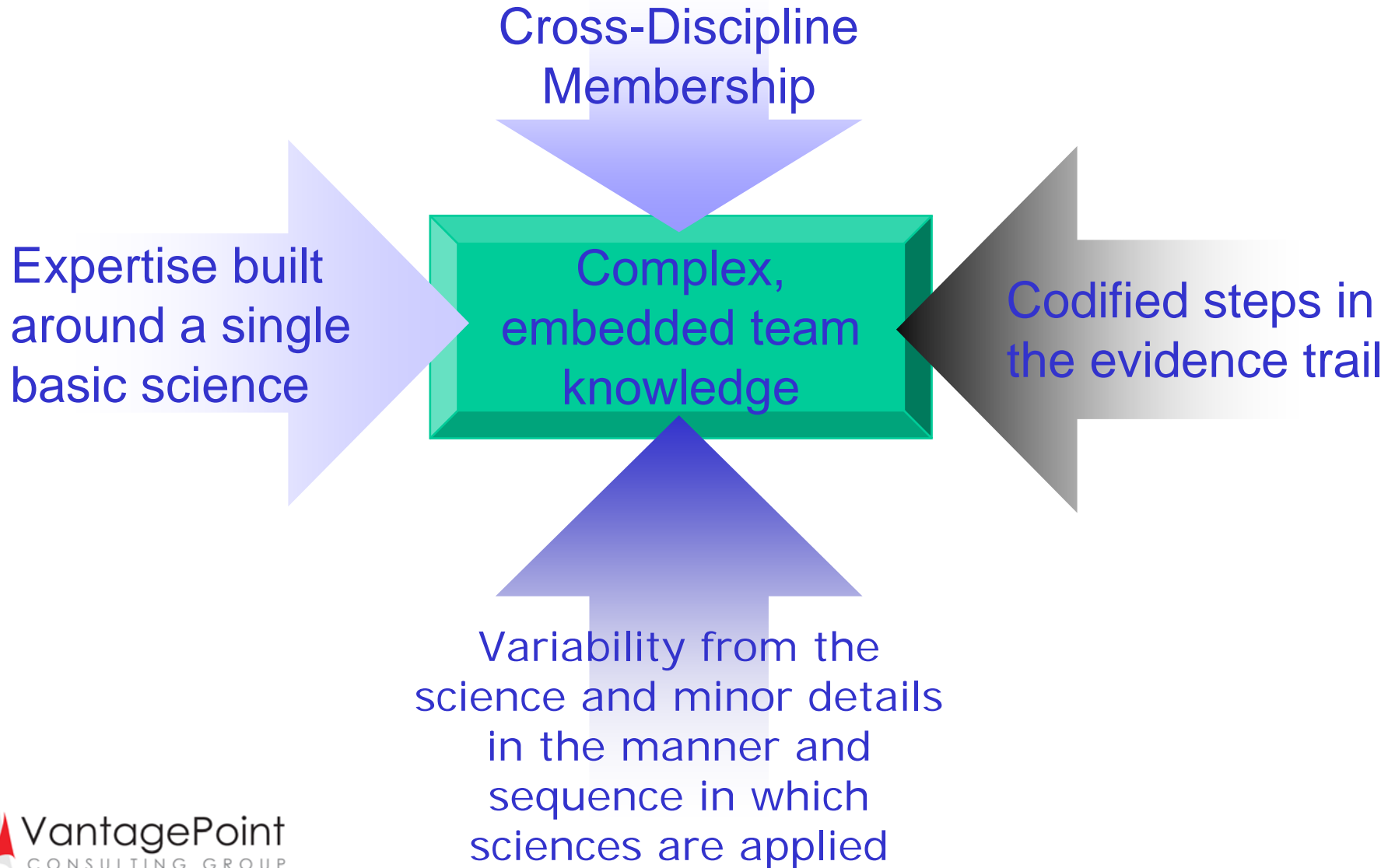
## LGCM

- Direct costs
- Budgetary Caps
- Confirming vs. Full Release

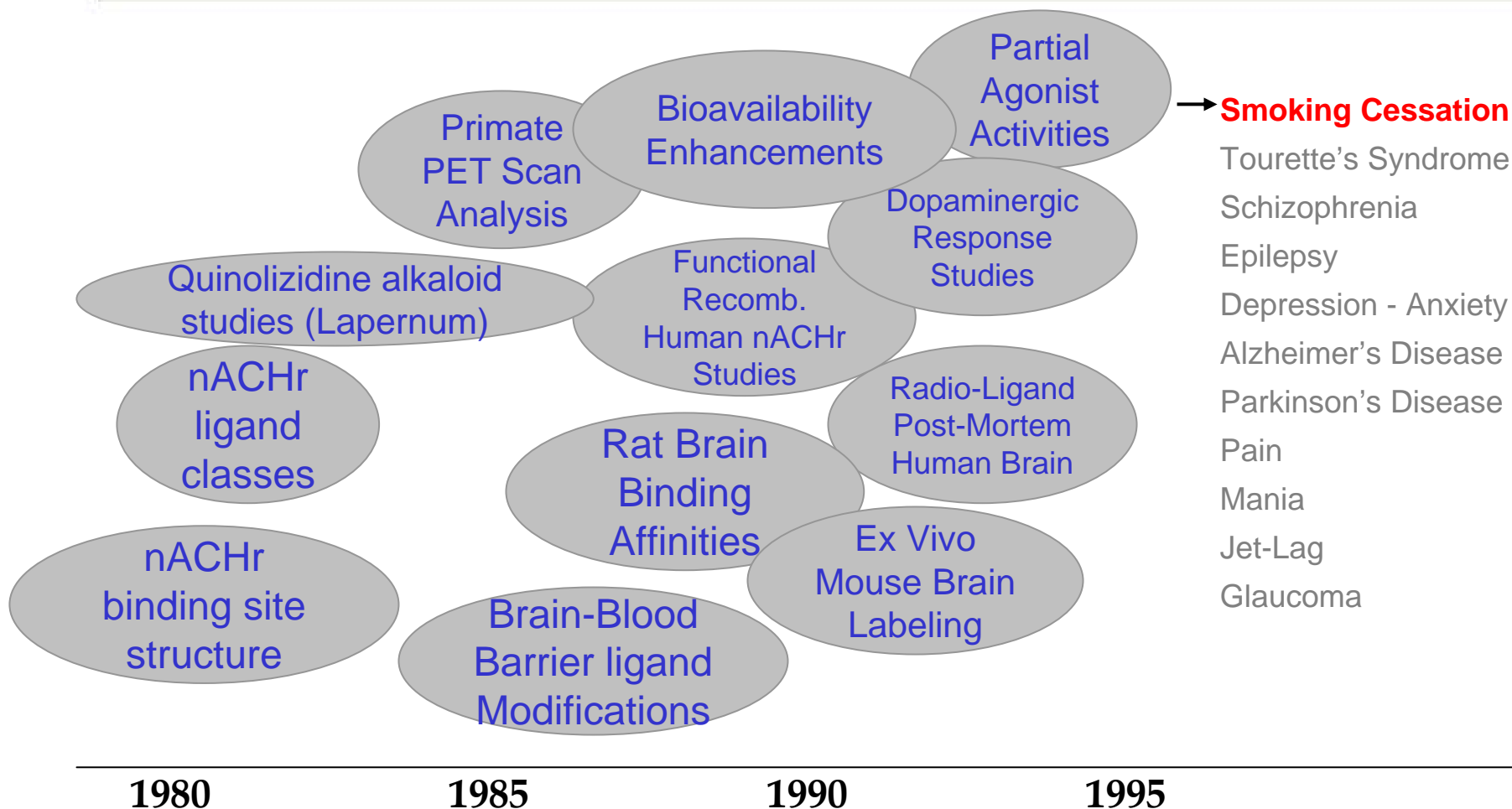
# Mission



# Knowledge Acquisition

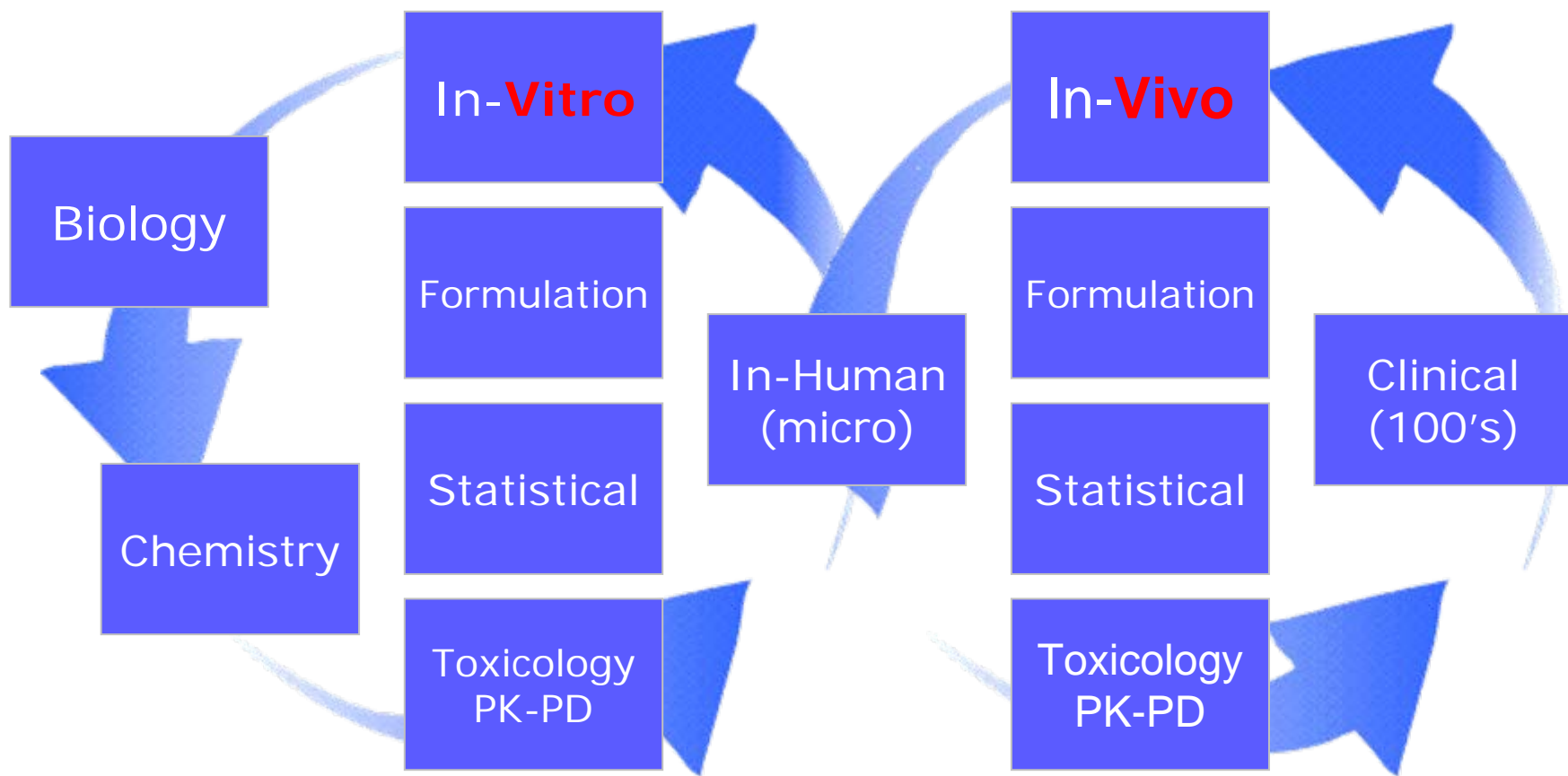


# Evidence Trail



Source: Novel Nicotinic Acetylcholine Receptor Ligands based on Cytisine and Choline: Synthesis, In vitro Evaluation and Structure-Activity Relationships - Lenka Munoz, Rheinischen Friedrich-Wilhelms -Universität Bonn, Nov. 2005

# End Point Selection



# Company Updates

**Wyeth**

