The Issue: The Number of New Drugs Reaching the Market is in Decline

According to a 2006 PricewaterhouseCoopers worldwide survey, although research and development (R&D) expenditure has risen steadily since 1990, the number of new drug approvals (NDAs) has dropped.

The Current Model at DTP Discovery

**Prospective to Late Screen:**
- All human cancer cell lines from 8 diseases, including leukemia, colon, and breast.
- A 5-step process combining traditional and high-throughput techniques.
- A 5-step development process with a successful drug discovery rate of 0.002%.

What are the main reasons that the development of potential drugs has stopped?

- **New drug approvals (NDAs) has dropped.**

NCI Goal

Increase the number of new anticancer interventions available to the patient.

DTp Goal

Increase the number of new, targeted anticancer therapeutics reaching clinical trials.

Reasons to Adopt the PK/PD Paradigm

**Efficacy considerations**—biometric, toxicology considerations—lack of predictability, and desire for targeted anticancer drugs.

Clinical Dose Basis for Guided PK/PD Phase II Studies

Dose elevations for the drug in question that produces an effect on a sensitive endpoint.

Developmental Therapeutics Program of the National Cancer Institute

Clinical Development of Therapeutics at the National Cancer Institute

Fate of Human Molecular Entities

- New drug approvals (NDAs) has dropped.
- NCI Goal: Increase the number of new anticancer interventions available to the patient.
- DTP Goal: Increase the number of new, targeted anticancer therapeutics reaching DTP Goal.

Adoption of the PK/PD development paradigm will decrease time and financial costs:

- Scale dosing scheme to the drug concentration that produces an effect on the molecular target.

**Cost:** $100,000 per drug vs. $1,000,000 per drug

**Conclusion**

Adoption of the PK/PD development paradigm will decrease time and financial commitment and will bring about the rapid translation of new, targeted anticancer drugs that reach clinical trials.