Drug Development: Translational Research and Academic-Industry Collaboration

Seth R Stevens, MD
Director, Medical Affairs
Amgen Inc
Important Note

This presentation includes a brief backgrounder for Amgen Medical Affairs personnel to use when introducing Amgen’s Policy on Interactions with Healthcare Professionals to current and potential research partners.

This presentation is not intended to provide legal advice.

Persons and entities engaging in transactions with Amgen should consult their counsel to ensure the proposed arrangement meets their own standards and understanding of the law.
Simple Model of Drug Development

Bench → Bedside
Comparison of Model and Disease

Model

A
B
C

Disease

? 
? 
? 
1
2
3
Translational Research

Model  Disease

A  ->  ?
B  ->  ?
C  ->  ?
?  <-  1
?  <-  2
?  <-  3
Translational Research

Intervention

Bench
Bedside
Translational Research

What do therapeutics need to do to work?
1. Achieve effective plasma level
2. Effective concentration for effective duration at target site
3. Drug-target interaction take place
4. Desired biologic effect
Translational Research

Successful Clinical Trial
- Predict responses
- Isolate other targets in pathway
- Clarify MOA/Pathophysiology

Failed Clinical Trial
- Alternative pathways
- Alternative metabolism
Overcoming Barriers

Interdisciplinary Teams

Laboratory-based investigators
  Preclinical validation
  In situ biomarker assessment
  Surrogate endpoint measurement

Clinical Investigators
  Plan and execute clinical trial
  Imaging/interventional radiology
  Pathology
  Molecular pathology

Statisticians
Research Nurses
Data Managers
Project Managers
Others
Physicists
Bioinformatics

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Understanding Industry

• Legal and Regulatory Environment
  – Anti-Kickback Laws
  – Off-label Promotion Laws
The Anti-Kickback Law prohibits payment of any remuneration, direct or indirect, in cash or in kind, in order to induce any person to use or recommend the use or purchase of Amgen products that may be paid for by Medicare, Medicaid or other federal health care programs.

Almost any payment or benefit given to a Customer or potential Customer could be viewed as payment for business if it is substantial enough to affect the recipient’s judgment.

Penalties under this law are severe, and can include the following:
- Prison
- Civil and criminal fines
- Exclusion from the Medicare Program and other Federal health care programs
Off-Label Promotion

- Misbranding
- Introduction of an unapproved drug into commerce
- False Claims
Some requirements

Best evidence
• Study design
  – Rigor (if not RDBPCT, why not?)
  – Size
• Likely to produce useful new information

Appropriate interactions
• Of interest to the company
• Fair market value
• Written agreement
Summary

Translational research is complex.

Effective collaborations between academics, industry and government will bring necessary components together.

Different cultures and demands must be understood and respected to maximize benefits from these collaborations.