RESEARCH COLLABORATIONS WITH INDUSTRY

Benefits and Risks


Research Management Architecture And All That Jazz!
2019 Midwest/Northeast Section Meeting
CHICAGO
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Objectives:

- Understand why organizations with disparate goals are willing to work together
  - Benefits
- Provide an overview of the issues
  - Risks

- Discussion of how to overcome obstacles

Many industry/academic partnerships

- Agriculture/agribusiness
- Engineering
  - e.g., aerospace, automobile, electronics, artificial intelligence (AI)

- **Biotech/drug discovery**

Academic Mission

- Example:
- Johns Hopkins University (https://www.jhu.edu/):
  - *To educate its students and cultivate their capacity for lifelong learning, to foster independent and original research, and to bring the benefits of discovery to the world*

- *Knowledge for the World*

Industry Mission

- Example:
- Gilead Sciences, Inc. (https://www.gilead.com/)
  - *To discover, develop and commercialize innovative therapeutics in the areas of unmet medical needs that improve patient care.*

Scientific Direction

- Translational research is the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs. Unlike applied sciences, translational research is specifically designed to improve health outcomes. It uses an integrated team of experts who are focused on translating useful information from laboratories to doctors' offices and hospitals. It's a "**bench to bedside**" bridge.
  - (https://www.ucdavis.edu/one-health/translational-research/)

Furthering translation

- The National Center for Advancing Translational Sciences (NCATS) — one of 27 Institutes and Centers at the National Institutes of Health (NIH) — was established in 2011 to transform the translational process so that new treatments and cures for disease can be delivered to patients faster.
  - Mission: catalyze the generation of innovative methods and technologies to enhance development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.

- NIH Roadmap 2004
  - transform the way biomedical research is conducted
  - High Risk/High Gain
- Clinical Translational Science Awards 2006
  - Today over 50 CTSA hubs
    - develop innovative solutions to improve the efficiency, quality and impact of the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public

Finding Synergy

- 2011
- National Center for Advancing Translational Science (NCATS) partners with pharmaceutical industry

- Changing ecosystem
  - Rise in academic drug discovery
- Partnerships with industry
- Start up companies/business development

Terms to remember

- FDA – Food and Drug Administration
- IND – Investigational New Drug
- IDE – investigational Device Exemption
- Phases of Clinical Trials
  - Pilot (Phase 0) first in people
    - learn how a drug is processed in the body and with what affect; a very small dose of a drug is given to about 10 to 15 people. Informs a go/no go decision

Terms to remember

- Phase I
  - an experimental treatment on a small group of often healthy people (20 to 80) to judge its **safety** and side effects and to find the correct drug dosage

Terms to remember

- Phase II
  - uses more people (100 to 300). emphasis on **efficacy**. Aim is to obtain preliminary data on whether the drug works in people who have a certain disease or condition. These trials also continue to study safety, including short-term side effects. This phase can last several years.

Terms to remember

- Phase III
  - gathers more information about safety and efficacy; studies different populations and different dosages and, in some cases, using the drug in combination with other drugs. Participation ranges from several hundred to about 3,000 people.
    - If the FDA agrees that the trial results are positive, it will approve the experimental drug or device.

Terms to remember

- Phase IV (postmarketing)
  - takes place after the FDA approves use. A device or drug's effectiveness and safety are monitored in large, diverse populations. May be longitudinal to learn side effects, which may not become known until taken over a long period of time.

Terms to remember

- Bayh-Dole
  - The **Bayh–Dole** Act or Patent and Trademark Law Amendments Act (Pub. L. 96-517, December 12, 1980) is United States legislation dealing with intellectual property arising from federal government-funded research.
    - Sen Birch Bayh, Indiana
    - Sen Bob Dole, Kansas
  - https://fas.org/sgp/crs/misc/RL32076.pdf

Terms to remember

- ROI – return on investment
  - Knowledge for the sake of enlightenment is insufficient (refer to Bayh-Dole)


Is CLINICAL RESEARCH
right for me?
Clinical research is medical research that involves people.

Drug Discovery and Development

- Average Cost to discovery/development:
  - $1-2 Billion
- Average time to discover/develop a drug:
  - 15 – 20 Years
- Average failure rate:
  - 95%

Cost per drug approved

Phase of Discovery/Development	Average Cost ($M)
Target to drug screening hit	$1
Screening hit to lead	2.5
Lead to clinical candidate	10
Candidate to IND filing	5
Phase I	15
Phase II	40
Phase III	150
NDA filing/launch	40
Market	264

Data from Nat. Rev. Drug Discovery 9, 203 (2010)

Time to market

Target to lead drug	1 - 5 years
Lead to IND	1 -3 years
Phase 1	1 year
Phase II	1 -3 years
Phase III	3 - 5 years
FDA review and approval	1 year (+/-)

Reasons for failure

- Half-life too short/long
- Not orally bioavailable
- Toxicity in people/animals
- Estimated return on investment (ROI) not adequate
- Insufficient efficacy advantage

  – The more failures in drug discovery and development, the more the cost of a new drug

AUTM*

- Established 1970s
  - developed best practices for university technology transfer offices
    - Facilitates relations with industry
    - Ideas to opportunities
    - Products, services, start-ups
  - Generating economic development
  - *Association of University Technology Managers

The divide

- Potential conflicts and challenges
- Legal and ethical implications
- Terms and conditions

potential conflicts and challenges

- Different goals
  - First to market v publication
  - Profit v scientific recognition (Nobel, Lasker)

legal and ethical implications

- October 2, 2014 The Physician Payments **Sunshine Act** - or, simply, the **Sunshine Act** - is an extension of the Patient Protection and Affordable Care **Act**
  - Aim is to increase public transparency for the transactions made between healthcare providers and other individuals and corporations.
- March 30, 2010 Health Care and Education Reconciliation Act a/k/a "Affordable Care Act" is usually used to refer to the final, amended version of the law. (sometimes known as "PPACA," "ACA," or "Obamacare.")

Terms and conditions

- Contractual agreements set conditions
  - May not be what researcher discussed with industry partner
- Typical issues:
  - Intellectual property ownership
  - Publication
  - Indemnification
  - Confidentiality
  - Governing law and venue
  - Warranties

Considerations

- Single site or multiple parties
  - Subcontracts
- Multi-center clinical trials
  - Who controls the sites?
  - Consortium - consider the needs of partners

Intellectual Property

Industry position

pay for it; own it

Research position

intellectual capital contributes to IP; ownership all depends; industry is paying for expertise

Variables

whose protocol is it?

who holds IND?

Publication

- Principles guided by the profession
  - e.g., International Committee of Medical Journal Editors ("ICMJE")
    - Rules of authorship – must be able to take public responsibility for the content
    - Research must be reproduceable -- informed by publication
  - Industry cannot control content
    - Review to protect its own proprietary information
    - May offer comment

Indemnification

- Agreement to make whole against any loss or damage the other party has incurred
- Reimbursement for such loss or damage

- Exclusions may apply

Confidentiality

- Determine what is “confidential”
  - Protocol, study design, business information, trade secrets
- Time limited
- Exclusions

Warranty

- Implied or explicit
- Most research and/or provision of experimental materials provided without warranty

Governing Law/Venue

- Law that controls interpretation of the agreement
- Venue – location for any litigation
- Option is to remain silent

REFERENCES/RESOURCES/ ACKNOWLEDGEMENTS

- https://uidp.org/
- https://autm.net/
- https://ico.sites.stanford.edu/
- Dr. Barbara Slusher, Professor, Director, Bsi NeuroTranslational Drug Discovery Program
- https://www.nccn.org/default.aspx
- https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies
- www.clinicaltrials.gov

Thank you!

- Questions?
- Now
- Later:
  - gmwalters@jhmi.edu