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Acknowledgements

Except where noted, no compensation, in any form, was paid to these individuals

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Acknowledgements (continued)

- UIDP is also grateful to those who were interviewed for the video portions of this module: **Mark Breedlove**, vice president, Vascular Division, Cook Medical; **Andy Dahlem**, PhD, former VP and COO, Lilly Research Laboratories (LRL) and LRL Europe; **Richard Gunderman**, MD, PhD, professor and vice chairman, Department of Radiology, Indiana University;
- **Jennifer Kerr**, president, Cook Research; **Anantha Shekhar**, MD, PhD, executive associate dean for research and director of the Indiana Clinical and Translational Sciences Institute, Indiana University School of Medicine; **Ronald G. Tompkins**, MD, ScD, Sumner M. Redstone Professor of Surgery, Harvard Medical School. Biographical information about the speakers is included later in this module.
- Thanks also to **Keith Davis**, PhD, director, Johnson Center for Innovation and Translational Research, Indiana University, who conducted video interviews at Cook Medical in Bloomington, Indiana.

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Acknowledgements (continued)

- UIDP also thanks the project co-leads **Ruben Rathnasingham**, PhD, assistant dean for health product innovation and director of the Texas Health Catalyst, Dell Medical School, University of Texas, Austin; and **Bruce Gingles**, vice president, global technology assessment and healthcare policy, Cook Medical. Also, many thanks to working group member **Chad A. League**, Esq., manager, Office of Contracts and Grants Management, Medstar Health Research Institute (MHRI).
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UI  Projects

UIDP Partnering with Industry: Best Practices Module

Purpose: To familiarize learners with how to form partnerships between Academic Medical Centers and Industry.

Format: Video interviews, case studies, list of resources, evaluation survey.

Estimated time to complete module: 15-20 minutes

PARTNERING WITH INDUSTRY: BEST PRACTICES

**ACADEMIC MEDICAL CENTER-INDUSTRY
ENGAGEMENT PROJECT**

WHAT ARE THE LEARNING OBJECTIVES FOR THIS MODULE?

The learner will understand:

1. The benefits of academic medical center-industry partnerships
2. How academic medical centers fit into industry's external partnership strategy
3. How industry identifies potential partners
4. When to approach industry
5. How to approach industry
6. When to publish research results
7. How physician entrepreneurs turn their ideas into patient-benefitting products
8. Things to consider when engaging with industry

Benefits of Academic Medical Center-Industry Partnerships

Key benefits of Medical School-Industry Collaboration

- Clinical concepts that envision a new drug, device or diagnostic frequently originate in the minds of physicians. **Academia can provide new ideas** for industry to act upon.
- **Collaborations enable industry to amplify their research investment** because academic researchers bring skills and clinical research qualifications that do not exist in industry.
- Most academics lack the expertise to scale up new ideas for production. **Industry plays a vital role in transforming an idea into a tangible product that benefits patients.**
- **Industry and academia can work together** to share best practices and ideas for advancing patient care.
- Industry has the **focused expertise to develop learning materials to support professional medical education.**

Here is what experts at Academic Medical Centers have to say:

**Richard Gunderman, MD, PhD Chancellor's Professor of
Radiology, Pediatrics, Medical Education, Philosophy, Liberal
Arts, Philanthropy, and Medical Humanities and Health Studies
at Indiana University**

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To summarize, Richard Gunderman's comments:

- Collaboration between academic institutions and industry in research is absolutely vital.
- Most academics lack expertise when it comes to scaling up a new idea for production.
- Industry plays a role in terms of translating a product or idea to something that could actually be produced for the benefit of patients.

Benefits of Academic Medical Center-Industry Partnerships

**Andy Dahlem, PhD, President , Dr. Dahlem Consulting,
former Vice President and Chief Operating Officer for Lilly
Research Laboratories (LRL) and LRL Europe**

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To summarize Andy Dahlem's comments:

- It costs too much and takes too long to discover new medicines today.
- Industry is looking for alternatives that can help in the journey to discover and develop new medicines and get them to patients.
- The external environment presents a unique opportunity where industry needs solutions, particularly in drug discovery and development, and where academia could collaborate with industry.
- Academia can solve funding challenges by collaborating with industry.

“Nuts and Bolts” of Partnering

Let's take a closer look at the “nuts and bolts” of partnering

We've asked experts at academic medical centers (AMC) and industry:

- How AMCs fit into industry's external partnership strategy
- How industry identifies potential partners
- When to approach industry
- How to approach industry
- When to publish research results
- How physician entrepreneurs turn their ideas into patient-benefitting products

Key Issues in Partnerships

Key Issues in Partnerships

Jennifer Kerr, President of Cook Research

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How Industry Identifies Potential Partners

How Industry Identifies Potential Partners

Jennifer Kerr, President of Cook Research

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When to Approach Industry

When to Approach Industry

Mark Breedlove, Vice President, Vascular Division (Vice President and Global Leader for the Peripheral Interventional Division at time of interview), Cook Medical

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[Click here to read transcript of interview.](#)

How to Approach Industry Partners

How to Approach Industry Partners

**Anantha Shekhar, MD, PhD, Associate Vice President of
Research for University Clinical Affairs, Indiana University
School of Medicine**

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How Physician- Entrepreneurs Turn their Ideas Into Patient- Benefitting Products

How Physician-Entrepreneurs Turn their Ideas Into Patient-Benefitting Products, Part I

Doug Raines, MD, Edward Mallinckrodt Jr. Professor of Anesthesia in the Field of Pharmacology and Innovation at Harvard Medical School

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How Physician Entrepreneurs Turn their Ideas Into Patient-Benefitting Products, Part II

Ronald G. Tompkins, MD, ScD, Sumner M. Redstone Prof. of Surgery, Harvard Medical School; Founding Dir., Center for Surgery, Science & Bioengineering at Mass. General Hospital; and Chief of Staff Emeritus, Shriners Hospitals

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Case Studies

Case Studies

What have other AMCs and/or their entrepreneurially minded faculty and students done to successfully engage with industry and align their research to their needs?

How have they resolved their “pain points”?

The following case studies are based on actual examples from Academic Medical Centers.

Case Study #1

Research Proposal: A medical school clinician researcher proposed a novel target for Parkinson's disease.

Gap Analysis: The proposed compound is owned by a private biotechnology company focused on Alzheimer's disease. Issues of intellectual property (IP), licensing and commercialization had to be addressed to ensure a successful research and development effort.

Activities: Through the medical school innovation program, the researcher met with an industry expert in neurodegenerative disease who had extensive experience in brokering industry-academia partnerships. Citing the time-consuming challenges of performing research with drugs owned by a different entity, the expert outlined a partnership between the investigator, the private company, and the Michael J. Fox Foundation.

Case Study #1 (cont.)

Outcome (over 6 – 24 months): By aligning research and business interests, the effort led to a strategic partnership with the private company and the creation of a robust development plan that garnered \$1M in funding from the Michael J. Fox Foundation.

Case Study #2

Research Proposal: A medical student and academic researcher developed a novel catheter-based filter that absorbs chemotherapeutic agents downstream of the target organ, minimizing systemic adverse events.

Gap Analysis: Although preliminary in-vitro data was compelling, the review panel had clinical, technical and commercialization concerns. The selectivity of the filter, the pressure drop across the filter, and the large scale manufacturability of the proposed design were key technical challenges. There was no existing IP and the potential for new IP was unclear. The impact of removing drug from the system on regulatory approval and clinical utility were further concerns.

Activities: Through the university's technology transfer office, the academic team met a veteran catheter-based device innovator with access to prototyping facilities and an oncologist and biotech executive. They worked closely to develop new devices designed for manufacturing and incorporated known materials and processes. They also outlined a target product profile that was attainable and accounted for potential hurdles in clinical adoption. They collaborated to submit a National Institutes of Health (NIH) grant and received funds to conduct large animal studies with their new prototypes.

Case Study #2 (cont.)

Outcome (over 6 – 24 months): Multiple prototype devices were developed for large animal studies. Ongoing large animal studies have pointed to improvements in filter design to create new IP.

The biotech executive and academic team created a new company that garnered a further \$225,000 NIH Small Business Technology Transfer (STTR) award to support investigational device exemption (IDE)–enabling studies. The positive results led them to a partnership with a medium-sized device company that worked with them to conduct clinical studies.

Case Study #3

Research Proposal: An academic researcher and clinical investigator proposed to study allogeneic human mesenchymal stem cells for the treatment of acute lung injury.

Gap Analysis: They were fortunate to meet an industry expert at a conference who recognized the value of the research but who also highlighted several potential hurdles to future development and commercialization. One hurdle involved an important IP conflict that could prevent marketing of a resulting product. The other hurdle involved the outcome of an FDA pre-investigational new drug (pre-IND) meeting, which required careful interpretation and a follow-up research plan to enable a Phase I clinical study.

Activities: The industry expert introduced the research team to technical and regulatory experts with relevant industry experience to help negotiate these critical development challenges. The industry expert also supported them with corporate funding through a sponsored research mechanism to conduct large animal and a Phase I clinical trial.

Case Study #3 (cont.)

Outcome (over 6 – 24 months): The industry expert helped the researcher design pre-IND enabling large animal studies and develop a pre-IND package for the Phase I clinical trial that was approved without any comments.

The Phase I study was successfully completed in early 2014 and Phase II studies are ongoing with the support of \$3M in follow on funding from the National Heart, Lung, and Blood Institute. The results have led to new findings and IP around the key composition of the proposed product.

Case Study #4

Research Proposal: A medical student and clinician researcher developed a delivery device and sealant to protect the amniotic membrane for pre-natal diagnosis and fetal therapy.

Gap Analysis: There were serious concerns about the market size and clinical adoption for the proposed combination product. Furthermore, the proposed sealant was a proprietary material and the design of the delivery system was rudimentary and unproven, raising concerns for the creation of new IP.

Activities: Through a university partnership event, the research team met with a device designer, a medtech executive, and an IP professional. Together they helped segment the market and identify and quantify the largest unmet need for the proposed product – fetal surgery as opposed to amniocentesis. They also helped identify the delivery device as the key to making the proposed product effective and clinically viable. They were able to collaborate on a grant application and received funds to design and test a delivery device that would meet key specifications.

Case Study #4 (cont.)

Outcome (over 6 – 24 months): The academic-industry team used the funds to determine the best positioning system for the device and created novel IP that could be broadly applied to the delivery of any material between distinct tissue interfaces. They went on to garner an additional \$600,000 in National Science Foundation funding to support product and clinical development of this novel device and the technology was then licensed by the industry partner.

Case Study #5

Research Proposal: A bioengineer and vitreo-retinal surgeon jointly developed a biodegradable drug-device combination product that enabled controlled release of small and large molecule drugs to the back of the eye. The product had the potential to improve clinical outcome and minimize risk to the patient in a multi-billion dollar market, while reducing treatment burden on clinicians.

Gap Analysis: The team recognized the potential commercial value for such a product, but received preliminary feedback from industry experts they met at a startup pitch competition who highlighted critical development hurdles which included: long term device-related safety concerns, large-scale process development, competitive advantage, and an unclear regulatory strategy.

Activities: With help from these industry experts, who had extensive product development and commercialization expertise in ophthalmology, the researchers engaged with key individuals in the U.S. Food and Drug Administration (FDA). The FDA provided feedback on a potential regulatory pathway and outlined development milestones to address critical risks early in the project. They received research funding from one of their industry sponsors to conduct well-defined pre-clinical studies.

Case Study #5 (cont.)

Outcome (over 6 – 24 months): Beyond the pre-clinical study, the industry sponsor helped the team articulate the target product profile and commercialization strategy to garner \$550,000 in product development funding from the Coulter Foundation. The technology is being spun out into a startup company and the team is in negotiations with several strategic partners to conduct clinical trials for multiple indications.

Things to Consider

Things to Consider

Jennifer Kerr, President of Cook Research

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Conclusion

Conclusion

There are many benefits of academic medical center-industry partnerships. Ultimately, the biggest benefactors are the patients who benefit from the resulting commercialized products. These partnerships also benefit academia, which otherwise might not have the expertise needed to translate knowledge into patents and other innovation building blocks. Industry benefits from the pipeline of innovations provided by academia and, in many cases, the ongoing expertise of academic researchers participating in the development process. When the fit between industry and academic partners is working well, both partners are fulfilling the mission and goals of their own organization.

Interviewees (in order of appearance)

No compensation was paid to speakers in this module.

Andy Dahlem, PhD

President, Dr. Dahlem Consulting

Former VP and COO

Lilly Research Laboratories (LRL) and LRL Europe

Mark Breedlove

Vice President, Vascular Division

Former Vice President and Global Leader

Peripheral Interventional Division

Cook Medical

Richard Gunderman, MD, PhD

Professor and Vice Chairman

Department of Radiology

Indiana University

Jennifer Kerr

President of Cook Research

Doug Raines, MD

Edward Mallinckrodt Jr. Professor of Anesthesia in the Field of Pharmacology and Innovation

Harvard Medical School

Anantha Shekhar, MD, PhD

Associate Vice President of Research for University Clinical Affairs

Indiana University School of Medicine

Ronald G. Tompkins, MD, ScD

Sumner M. Redstone Professor of Surgery

Harvard Medical School

Resources

Resources

Foundation for the Advanced Education in the Sciences (FAES) courses on technology transfer <https://faes.org/content/graduate-school>

UIDP Researcher Handbook and Quick Guide

<https://www.uidp.org/publication/researcher-guidebook-and-quick-guide/>

Evaluation Survey

Please take our 2-minute evaluation survey [here](#).

About UIDP

The UIDP is a unique project-oriented forum where representatives from academia and industry seek opportunities to develop new approaches to working together.

Representatives of UIDP member organizations work together to:

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- Build new networks and opportunities for future collaborations
- Remove barriers to joint research project success

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