Working with Industry and Intellectual Property

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The STAR Certificate consists of 11 courses. To obtain a certificate, you must complete all 11 courses within two (2) years.

During this pandemic, the two year period has been extended per exceptions on a case by case basis. Please reach out to training@research.ucsb.edu for any exceptions.

For any STAR Program questions: Contact Clarissa Cabrera at training@research.ucsb.edu

Zoom Classes will not be recorded for this 2023 series.

Reminder to complete the STAR Evaluation. Emailed to registered participants via email used in UCLC.
Why do we work with Industry?
Benefits of Industry/University Collaboration

• Provide faculty with “cutting edge” experience with “real world” problems to enhance their teaching and research
• Help students gain valuable educational opportunities and gain marketability
• Develop ties to provide future funding to support new or ongoing research in areas useful to society.
Benefits of Industry/University Collaboration

- Facilitate informal technology transfer
- Offer research opportunities through which faculty can make contributions to knowledge.
- Assist in fulfilling the university’s mission for public service.
The University/Industry Challenge:

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<th>Industry</th>
<th>University</th>
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<td>• Closed environment</td>
<td>• Open environment</td>
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<td>• Hierarchical</td>
<td>• Non-hierarchical</td>
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<td>• Swift moving</td>
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<td>• Results-oriented</td>
<td>• Process and general knowledge oriented</td>
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<td>• Primary responsibility is to company bottom line</td>
<td>• Primary responsibility is to the public</td>
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Ways UCSB Works with Industry

What we’ll talk about today. . .

Part 1
• Gifts and Endowments
• Research Agreements
• Material Transfer Agreements
• Non-disclosure/Confidentiality Agreements
• Data Use Agreements

Part 2
• Technology Transfer
  (Intellectual Property Licensing)
• Faculty Consulting Agreements
Ways UCSB Works with Industry

Outline of a potential relationship with a single industry sponsor

- **NDA**: Allows company to share confidential info w/ PI to further discuss potential research opportunities & collaboration
- **MTA**: Allows company to share physical material with PI to allow for preliminary assessments
- **Sponsored Research Agreement**: Funding mechanism through which company agrees to fund a scope of work for a specified funding amount
- **IP License Agreement**: Company licenses IP which arose from scope of work performed under the Sponsored Research Agreement
Ways UCSB Works with Industry

Other ways...

- Use of certain facilities on a fee-for-service basis (e.g. UCSB “cleanroom” facilities)
- University-Industry exchange programs and student internships
- Participation of industry representatives on campus and university-wide advisory groups
Before We Begin:

- The common principle that guides all industry interactions, regardless of type:

  “..first consideration must be given to the University’s mission of teaching, research, and public service. In pursuing relationships with industry, the University must keep the public trust and maintain institutional independence and integrity to permit faculty and students to pursue learning and research freely.”

From UC Guidelines on University-Industry Relations (May 1989)
Gifts and Endowments
Gifts

- What they are: in general, research funds are classified as gifts when:
  - The donor does not impose contractual requirements in connection with the acceptance or use of the funds.
  - The funds are awarded irrevocably.
- May be in the form of funding, equipment, or other in-kind benefits.
- Indirect (F&A) costs are not assessed on gift funds.
- May be given as entirely unrestricted, or may be as specific as for use by particular research group for particular purpose.
Gifts: Benefits to Industry & UC

- Provides general support - use of the money is not restricted to a specific scope of work.
- Provides mechanism to assure UCSB’s research base in a specific area remains strong.
- Allows industry to build strong, close relationships with UCSB faculty.
- Through gifts which fund graduate students, industry can help create high quality future workforce.
Gifts From Industry : Challenges

• The Conflict of Interest (700U) review process does apply to gifts from industry.
• Donors are increasingly sophisticated.
  • Transactions start as “no strings” donations, strict contractual obligations creep in over time.
  • Requests for intellectual property rights in exchange. (It is against policy to honor this request.)
• Unclear whether it is a gift? See “Gifts, Grants, Contracts and Sponsorship Determinations” at www.policy.ucsb.edu (also included as handout for this presentation)
Industry Sponsored Research Agreements
Industry Research Agreements

• **What they are:** A written agreement between UCSB and an industry sponsor in which UCSB agrees to conduct a specific research project, over a defined period of time, in exchange for compensation, subject to mutually-agreeable contractual terms.
UCSB Industry Sponsored Research for FY2023

Total Awards
$257.6 M

Federal Flow-Through
$34.7 M
Higher Ed
$4.1 M
Non-Profit
$27.4 M
State
$7.4 M
Industry
$7.3 M
Federal
$171.8 M
UC
$4.9 M

Note*:

UCSB TIA-administered sponsored research agreements include direct industry + all industry “flow-through” + a few others

FY23: 15.5M
Types of Research Agreements with Industry

- Grants
  - Assistance funding provided to support research.

- Cost-reimbursement Contracts
  - Expenditures on project are reimbursed as incurred.

- Fixed-Price Contracts
  - Defined deliverables are produced by the University and the sponsor pays a pre-set amount for each deliverable/scope of work.

Note: Contract type is separate issue from payment terms (advance payments vs. reimbursements vs. milestone payments).
Essential Items addressed in Industry Research Agreements

- Intellectual Property Rights
  - Definition of IP, Ownership of IP, License Rights to IP
- Publication Rights
- Payment Terms
- Rights of Termination by either party
- Statement of Work/Deliverables
Research Agreements with Industry: Benefits

- Funds projects that Federal Agencies may not fund.
- More rapid proposal review - funding decisions are made more quickly.
- Administrative burden for Principal Investigator and Department is minimal (usually).
  - Statement of Work and Detailed Budget are typically all that is needed for negotiation.
  - Budget restrictions that apply to many federally-funded projects are usually not incorporated.
Research Agreements with Industry: Challenges

• Length of negotiations can vary (very) greatly.
• Strict contract provisions
  • based on private sector business/procurement practices (B2B transactions)
    • Terms need to be revised significantly in order to fit a contractual relationship with a university
      • Ex.: Purchase Order Terms & Conditions
  • designed to protect private sector interests
    • Unreasonable confidentiality provisions
    • Stringent documentation requirements
    • Anti-competition clauses
• Potential for negotiation impasse
  • May not be able to align interests or arrive at agreeable terms!
Challenges Specific to Federal Flow-through Industry Contracts

• T&Cs that the Federal agency gave to company are flowed down (unaltered) to university subcontractor (FAR clauses)

• Company’s own commercial procurement T&Cs are layered over Federal T&Cs
  • Potentially “the worst of the worst” for a university contractor.
International Challenges

- Different Business Processes/Forms
- Language
- Culture
Other Agreements

- Types of TIA-administered Other (Unfunded) Agreements:
  - Material Transfer Agreements (MTAs)
    - w/ all entity types
  - Non-Disclosure/Confidentiality Agreements (NDAs/CDAs)
    - w/ all entity types
  - Data Use Agreements/Data Sharing Agreements (DUAs/DTUAs)
    - w/ all entity types
  - Other
    - Research-related MOUs (with industry), Software License Agreements (from all entity types), IP Agreements (for STTR Programs), etc.
UCSB TIA-Administered Other Agreements for FY2023

- FY 2023 Other Agreement Numbers
  - 138 Incoming MTAs
  - 27 Outgoing MTAs
  - 62 NDAs
  - 21 DUAs
Material Transfer Agreements

addgene
The nonprofit plasmid repository
What are Material Transfer Agreements (MTAs)?

- A binding contract in which one party agrees to provide physical material to another party for testing, evaluation, experimentation, or other research purposes.
Key Parts of an MTA:

• Liability and intellectual property (IP) clauses
  • Both used to protect the Provider

• Scope of use for the materials
  • Sets parameters under which researcher and projects the material may be used
Types of MTAs:

- **Incoming MTAs:**
  - Provider is sending material to UCSB researcher(s)
  - Provider typically issues the MTA to UCSB

- **Outgoing MTAs:**
  - UCSB is sending material elsewhere (e.g. company, another educational institution)
  - UCSB issues MTA to receiving party
How do you get an MTA in place?

• Researcher needs to complete the MTA Request Form (found on the TIA website under “Forms & Policies”) and submit it to the TIA Industry Contracts group at mta@tia.ucsb.edu
  • Also include any related documents, such as the draft MTA from the provider (if incoming)

• Once initial intake process is complete, MTA/NDA Officer will review form and MTA terms and reach out to the provider/recipient to address any issues
## MTA Request Form

**Material Transfer Agreement Request Form**

### Section 1: Principal Investigator (PI) and Lab Contact Information
- PI Name
- PI Phone
- PI E-mail
- UCSC Department & Mail Code

### Section 2: Outside Organization Information
- Organization Name
- Address
- Legal Contact Name & E-mail
- Scientific Contact Name & E-mail

### Section 3: Details Regarding the Material
- UCSC will be:
  - [ ] Receiving Material (complete in Section 3 & Section 4)
  - [ ] Providing Material (complete in Section 3 & Section 5)
- Material to be used:
  - [ ] Plasmid or Viral Vector
  - [ ] Embryonic Stem Cell or Induced Pluripotent Stem Cell (iPSC)
  - [ ] Compound/Chemical
  - [ ] Cell Line
  - [ ] Human Specimen
  - [ ] Animal/Animal Specimen
- Scientific Description of the Material and Quantity to transfer/receive:
- Will the Material be coming from sources, or sent to entities, outside of the UCSC? [ ] Yes [ ] No
- Anticipated Time Period Material Will Be Used by UCSC/Organization:
  - [ ] Begin Date
  - [ ] End Date
- Are you receiving any funds, contract, grant, or gifts from the Outside Organization? [ ] Yes [ ] No

### Section 4: Questions for Incoming Material
- [ ] Is the Material intended for use in the laboratories of the PI?
  - [ ] Funding source

### Section 5: Questions for Outgoing Material
- [ ] Are you willing to charge a fee for the transfer of the Material? [ ] Yes [ ] No
- [ ] Did you receive the Material from others, and this is a re-transfer of the same Material? [ ] Yes [ ] No
- [ ] Does the Material contain materials received from others? [ ] Yes [ ] No
- [ ] Are you aware of any confidential agreements related to the Material? [ ] Yes [ ] No

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1. I certify that the information I have provided is an accurate reflection of my understanding.

   **Principal Investigator**

   **Date**

   **Revised March 1, 2022**
Instances when MTAs are **NOT** needed

- See *Research Circular E.1. - Section III* for details (included as a handout to this presentation)

- Transfer of material to a *nonprofit research organization* for that organization’s *internal research use*, provided that:
  - Prior to transfer of any animal materials, or materials that could be used in humans, researcher sending materials expressly tells recipient, in writing, the materials cannot be used in humans or further distributed.
Instances when MTAs are **NOT** needed (cont’d):

- Transfer of unmodified, naturally-occurring, non-hazardous materials that do not contain any human/animal tissue (e.g. a rock).
- Material sent to another non-profit for personal use by a UCSB researcher (e.g. sending ahead where faculty is going on sabbatical)
- Commercially available materials
- Transfer of purchased equipment/instrumentation for repair or replacement
- Transfer of documents
Exceptions to when “no MTAs are needed”

• Remember - even if an MTA is not needed, U.S. export control laws can still restrict the transfer of certain materials
  • Do not send materials outside the U.S. without first checking with the Export Control Officer in Office of Research’s Research Integrity group
• Outgoing MTAs are strongly encouraged, regardless of the “no MTA” policy, when the material relates to a patentable invention that has been disclosed by the UCSB researcher to TIA
A few other things to consider about Incoming MTAs

- Incoming MTAs can have complex terms that rival industry contracts
- The provider may ask for clauses that can directly injure research activities:
  - Publication restrictions
  - IP ownership
  - Free commercial use of discoveries
- If these types of issues are present in the MTA, they may affect the timeline to get the agreement in place or result in an impasse
A few other things to consider about Incoming MTAs (cont’d)

• Other approvals that may potentially relate to MTAs:
  • Human Subjects
  • Animal Subjects
  • Stem Cell Research Oversight Committee
  • Environmental Health & Safety
  • Conflict of Interest
  • Export Control
Things to remember with MTAs

• Researchers should not receive materials on campus until an MTA is legally in place

• PIs are not authorized to sign MTAs (i.e. researchers cannot legally bind the University to the MTA terms), only the MTA/NDA Officer can sign MTAs
  • If a researcher does sign, they are subjecting themselves to personal liability

• If a PI fails to get an MTA in place prior to using the material, this could jeopardize their research, ability to publish, and risk forfeiture of IP rights associated with the material

• Keep an eye out for the mention of materials in project proposals
Non-Disclosure/Confidentiality Agreements
What are Non-Disclosure or Confidentiality Agreements (NDAs/CDAs)?

• A legal agreement establishing that a receiving party will not disclose proprietary information shared by a disclosing party (may be unilateral or mutual)

• For UCSB’s purposes, we primarily use NDAs for two (2) reasons:
  1. A company wishes to review a patent application in order to determine if it wishes to license technology
  2. A company has confidential or sensitive information that may be relevant to University research, but the further disclosure of the information could hurt the company
How do you get NDAs/CDAs in place?

- PI needs to complete the NDA/Other Agreement Request Form (found under the “Forms & Policies” section of TIA website) and send it to the TIA Industry Contracts group at mta@tia.ucsb.edu
  
  - Similar to MTAs, provide any additional documentation related to the NDA as well

- Once the intake process is complete, MTA/NDA Officer will review form and the NDA and work with the researcher and other party to reach agreeable terms
Key concerns for NDAs/CDAs

- Clear marking requirements for confidential information
- Narrow, limited scope/purpose of NDA (specific researchers, no students, confidentiality terms don’t apply to UCSB-generated data and results)
- Export control (e.g. Technology Control Plan)
- Ability to publish
- Ability to follow safeguarding and storage requirements (e.g. data security)
A few reminders for NDAs/CDAs

• For any NDAs related to University research, PIs are not authorized to sign these agreements

• Time frame for negotiations varies, depends on terms and if additional approvals are needed (e.g. export control)
Data Use Agreements
What are Data Use Agreements (DUAs)?

- A binding contract between parties to define how data and/or data sets provided by one party (the “Provider”) can be used by the other party (the “Recipient”).
- A DUA can have terms that are important to review carefully including, but not limited to,
  - limitations on who can access the data,
  - whether and how the data can be published in academic writing, and/or
  - how the data must be physically secured and/or accessed.
- If the terms of a DUA are problematic, the Office of Technology & Industry Alliances will reach out to the provider to try to negotiate revised terms.
Types of DUAs:

• Incoming DUAs
  • The provider (whether a company, a nonprofit, governmental agency is sharing data/data sets with a UCSB researcher
  • Provider typically drafts and issues DUA to UCSB

• Outgoing DUAs
  • UCSB is sharing data/data sets with others (e.g. company, another educational institution)
  • UCSB will draft and issue DUA to receiving party
Types of Data Shared in DUAs

- Confidential/sensitive information
- Often, needs human subjects review/approval, for access to:
  - De-identified Data
    - Human Subjects Data where all 18 of the personal identifiers specified by HIPAA have been removed.
  - Limited Data Set
    - Human Subjects Data where certain identifiers have been removed
  - Protected Health Information/Personally Identifiable Information
    - Note: recommended that researchers should determine whether PHI/PII is actually necessary for the research project. Often, either a limited data set or completely de-identified data can be effective in the proposed research project, where the extra obligations and responsibilities associated with accepting PHI may not be necessary.
Key Considerations for DUAs

- Legal terms similar to MTAs, NDAs, and SRAs
- Special data security provisions and/or human subjects protection requirements that may require coordination with different campus departments and units including:
  - Research Integrity (Office of Research)
  - The researchers’ respective departmental IT groups
  - Enterprise Technology Services (ETS) group, and/or
  - Secure Computing Research Environment (SCRE).
- For DUAs from some governmental and state agencies, may require signature of the UCSB Information Security Officer (ISO) and the Senior Official (SO)
  - All DUAs that require security signoff must follow the process implemented by the UCSB Office of Information Technology. See UCSB Datasets Signoff Process.
Key Considerations for DUAs

- For transfers of data/data sets from UCSB researchers to another party (Outgoing Data):

  - An Outgoing DUA must be put in place for any data is transferred if
    - Any of the data is from human subjects; and/or
    - The data to be transferred is HIPAA protected.

Note: If the data to be shared is completely de-identified and there is no means to re-identify, a DUA is not needed. To meet this qualification the data must be stripped of the data elements cited above in personally identifiable information. If the data contains any of these identifiers then a DUA must be in place. DUAs must also be in place if sponsored funding was involved and there are data ownership and/or dissemination requirements.
How do you get a DUA in place?

• Researcher needs to complete the DUA Request Form (found on the TIA website under “Forms & Policies”) and submit it to the TIA Industry Contracts group (via e-mail to mta@tia.ucsb.edu)
  • Also include any related documents, such as the draft DUA sent by the provider, if for incoming data/data sets
• Once initial intake process is complete, TIA will review form and DUA terms and reach out to the provider/recipient to address any issues
**DUA Request Form**

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**Data Use Agreement Request Form**

**Principal Investigator (PI) and Lab Contact Information**

- **PI Name**
- **P.I. E-mail**
- **UCSB Department & Mail Code**

**Outside Organization Information**

- **Organization Name**
- **Address**
- **Authorized Official/Contact Name**
- **Home**
- **E-mail**

**Details Regarding the Data**

- **UCSB will be the owner of the PI, as applicable**
- **Description of the Data to transfer/receive**
  - Include if it involves human subjects, animal subjects, or any study to which data was obtained, any identifiers within the data.
- **Human Subjects Considerations**
  - **Identified Data about human subjects**
  - **Anonymized Data**
  - **Institutional Review Board (IRB) Number**
  - **Study Protocol Number**
- **Data Security Considerations**
  - **Confidentiality Agreement**
  - **Data Sharing Agreement**
  - **Data Transfer Agreement**

**Anticipated Data Use**

- **Data will be used for**
- **Data will be shared**
- **Data will be stored**

**Questions for Incoming Data**

- **Intended Use of the Data**
- **Scope of Work**
- **Mentoring**
- **Human Subjects Considerations**
- **Data Security Considerations**

**Questions for Outgoing Data**

- **Do you want to change the responsibilities of the Data?**
- **Data will be shared**
- **Data will be stored**

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**I certify that this information I have provided is an accurate reflection of my understanding.**

Principal Investigator

Date: [Redacted]

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**Revised April 14, 2021**
Questions?

TIA Industry Contracts
Contact Information

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But first... What is Intellectual Property?
Intellectual Property

• General Principles:
  • Intangible Piece of Property
    • May sell, license, assign, inherit, use as collateral
  • License v. Assignment
  • Exclusive v. Non-exclusive v. field of use
Types of Intellectual Property

- Patents
- Copyrights
- Trademarks
- Trade Secrets
Patents

• What do they cover?
  • useful processes, machines, manufactured items or compositions of matter

• What, exactly, are they?
  • A grant by the Federal Government of the right to EXCLUDE others from practicing an invention

• How long do they last?
  • Twenty years from the date they are filed.
Who Owns The Patent, UC or the PI?

• All UC employees, including faculty, sign a Patent Acknowledgement agreeing to assign title to all patents to UC.

• It is critical that ALL visiting researchers sign patent acknowledgments to prevent future disputes.

• Exceptions rarely granted, and can be granted only with the approval of the Director, UCOP OTT.
UC Patent Policy

Applies to:
• All Employees (including faculty and staff)
• Individuals using University research facilities
• Individuals receiving gift, grant, or contract funds through the University

Does NOT apply to:
• Students with respect to academic course work
  • Does apply if they are also employees (GSR, TA, etc.) or work on extramurally sponsored research
UC Patent Agreement (incorporated into UPAY585)

• Mandatory disclosure
• Agreement to assign inventions and patents to the University, except those resulting from permissible consulting activities without use of University facilities
• University agrees to share royalties, if any, with inventor(s).
• Exceptions to policy require approval of OTT Director, and are rarely granted.
• So, why all the fuss?
• Intellectual Property **can** be extremely valuable

• **Top 5 Income-Earning UC Patents (FY21)**

  • Opto-Electropositioning Microfluidic Chips (UCB & UCLA) **$17M**
  • CAR T Cell Therapy for Cancer (UCSF) **$13.7M**
  • Nephropathic Cystinosis Treatment (UCSD) **$10.8M**
  • Tango Mandarin (UCR) **$6.7M**
  • Bovine Growth Hormone (UCSF) **$5M**

• HOWEVER, most do not make money. UC has 13,000+ active patents (domestic & international).

• In FY21, the top 5 earned 39.1% of all income; the top 25 earned 63.1% of all income.

• **That said**, UC Inventor(s) receive: **35%** of net income (after patent costs) and companies prefer NOT to pay royalties, so if IP hits big, there is a lot at stake.
But if there’s not a lot of money, what’s the big deal?

• UC also wants title, for several reasons:
  • Assure it can transfer technology freely, for the public benefit;
  • Assure it’s research in that area continues unfettered;
  • Assure return on years of investment by taxpayers through licensing revenue
  • AND. . .our researchers developed it, our taxpayers helped subsidize it!
• It is UC policy to retain title to all patentable inventions.

• The industry partner may receive the following:
  • If it pays all costs, including academic year salaries, it may have a time-limited option to negotiate an exclusive or nonexclusive license.
The Patent Licensing Process:
What happens when researchers invent something?
Disclosure

Preliminary Evaluation
- Patentability Assessment/Commercial Potential
- Sponsor Commitments
- Tangible Research Products
- Invention Overlap

Obtain Patent(s)
- Inventor Leads
- Professional Contacts
- Mass Marketing

License or Option
- Grant
- License Issue Fee
- Prosecution
- Reimbursement
- Minimum Royalties
- Earned Royalties
- Diligence
- Reporting
- Problem Resolution

Secrecy Agreements

Commercialization
Other Intellectual Property

- Trademarks ® ™
- Trade secrets
- Copyrights ©
Trademarks

- Nike swoosh™
- Coca Cola® shaped bottle
- UCSB waves
- “A trademark is a distinctive mark of authenticity through which the products of particular manufacturers may be distinguished from those of others.”
Trade secrets

• Coca Cola formula
• KFC secret recipe

“A ‘trade secret’ means information, including a formula, pattern, compilation, program, data, device, method, technique, or process, that:

• 1. Derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and

• 2. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”
Copyrights

- Protects distinct categories of works
- Protection granted as soon as the work is expressed in a tangible medium
- Lifetime of the author + 70 years
- Works created in 1925 or earlier, and works created by federal government employees, are in the Public Domain
Faculty Consulting
Faculty Consulting Agreements

• **Private** legal contract between faculty member and a company (University not a party)
• May not use University facilities
• May not interfere with University responsibilities
• May not use “University” time, i.e., may only consult **39 days a year** (incl. weekends and holidays) (APM 025)
• Must disclose through Academic Personnel’s annual disclosure (managed at department level)
Issues Which Arise

• Faculty member required to assign inventions made while consulting to the company.

• Patent Policy says “assign inventions and patents to the University, except for those resulting from permissible consulting activities without use of University facilities.”

• Due to conflict of interest rules, accepting large consulting agreements can affect the researcher’s ability to accept research funds from that company for on-campus research.
Faculty Consulting: Resources

• “Guidelines on Faculty Consulting and Intellectual Property Policies,” located in the policy section of TIA’s website (tia.ucsb.edu) is an excellent compendium of the various policies that apply to faculty consulting.
IP Questions?

Contact UCSB Office of Technology & Industry Alliances

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