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Transforming Ideas into Opportunities



Big Data, Big Opportunity:

The What, How, Dos and Don'ts of Licensing Data



Speakers:



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What's the issue and why should I care?

Data license lawsuits

- *University of Chicago Medical Center & Alphabet, Inc. (Google) potential class-action lawsuit*
 - Claims medical school violated Illinois patients' rights law
 - U of Chicago allegedly sold health data without consent
- *MSK and Paige.AI licensing deal scrutinized*
 - Allegations of conflict of interest, private inurement



Data protection laws are being enacted throughout the world

- *EU's General Data Protection Regulation (GDPR)* – implemented May 2018
- *California's Consumer Privacy Act* – enacted Jan. 1, 2020

What we plan to cover:

What do we mean by, and what are the sources of, licensable “data”?

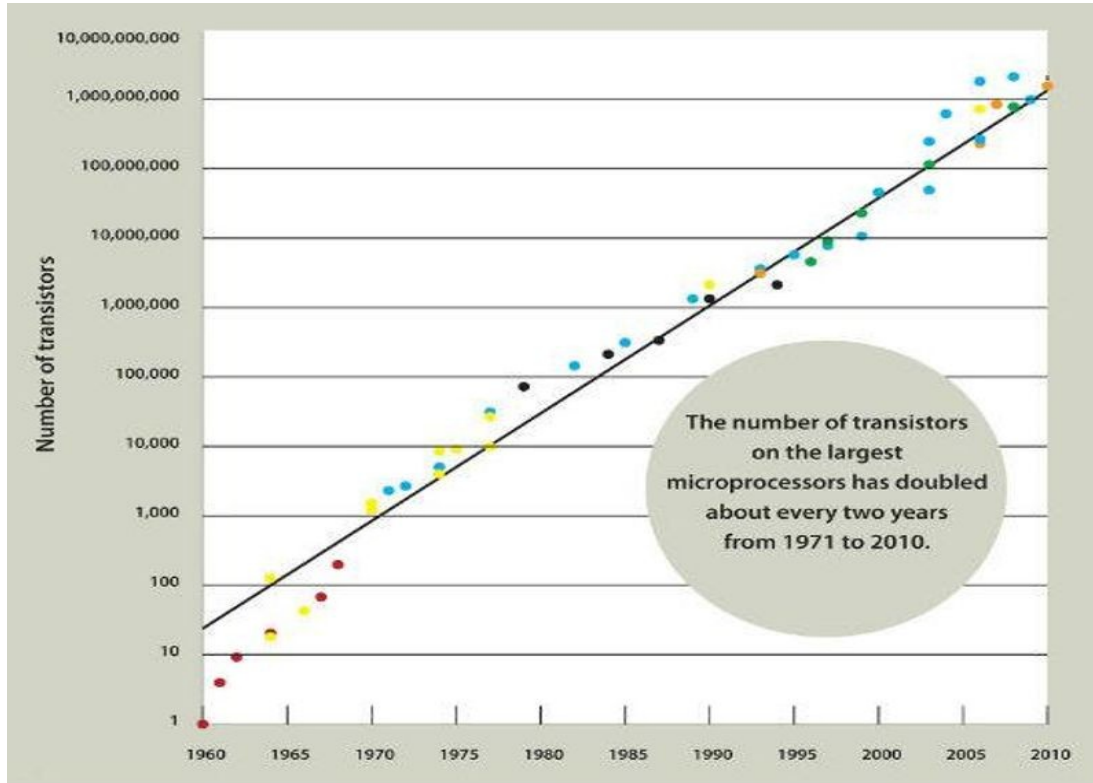
- **Step 1: Assessing your ability to license the data**
 - Can you license the data?
- **Step 2: Models for licensing the data**
 - How do you license the data?

Examples

What data assets are generated by universities?



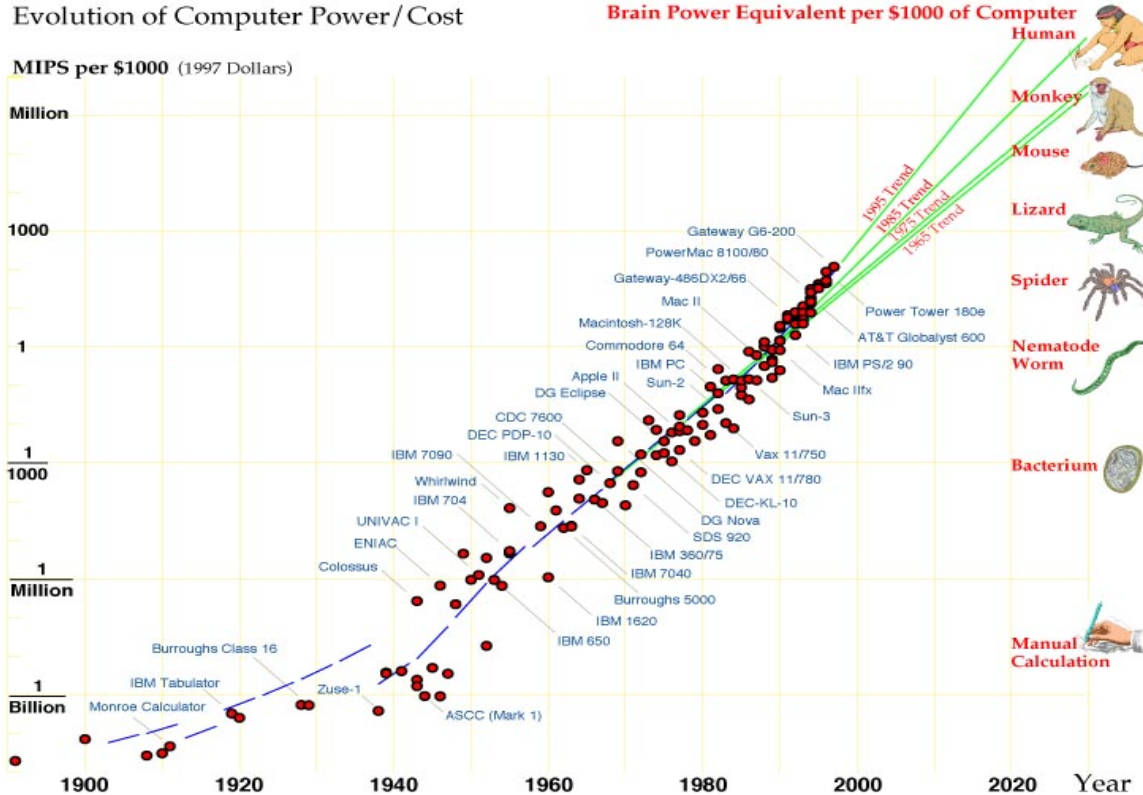
Is this really a new issue?



Hardware advancements have enabled storage and processing of massive datasets

163 **Zettabytes** by 2025
(1.63×10^{14} GB =
1630000000000000 GB)!!!

How did we get here? Cost Efficiencies



Step 1: Do you have rights you can license?

Licensees value data, but the data rights they want:

- Don't always align with IP rights
- Can be difficult for an academic institution to give

So, it is important to:

- Don't assume data rights are the same as copyright or patent rights
- Be aware of and explain limitations to licensees



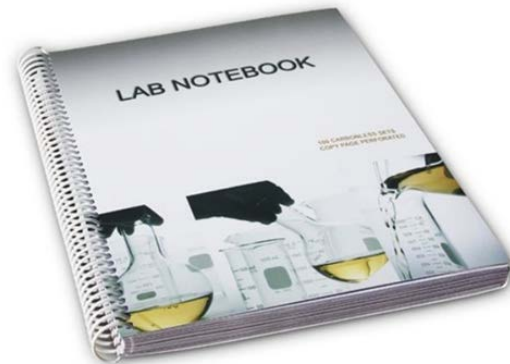
Step 1: Do you have rights you can license?

Generally accepted premises:

1. A institution can only grant a license to rights it actually owns or controls
2. Nonexclusive grants are preferable

But, licensees want to ensure:

- Complete and ongoing knowledge transfer
- R&D funding not wasted
- Freedom to operate



Step 1: Do you have rights you can license?

What does an institution "own" in data?

1. Not scientific "facts" or truths themselves...
 - a. E.g., merger doctrine in copyright
2. IP rights?
 - a. Copyright in compilation
 - b. Patent on results/insights from data
3. Contractual access and the right to possess?



Why data is challenging to protect:

Current § 101
challenges,
e.g., Athena

patent
rights

copyright

Contractual
"property"
rights

Limited scope &
enforcement

Challenges with protecting data...

- **University's inability to rely on trade secret law**
- **Unlike EU, U.S. has no data protection laws**
 - U.S. has rejected “sweat of the brow” data protection
 - EU has Database Directive (1996) = property right
- **Copyright? Enforcement is often incommensurate with value**
- **EU Proposal: “Data Producer’s Right”**

Contractual basis for rights in data

If licenseable rights exist, they are based in contract and can depend on many factors, including applicable law, policy, and circumstances of data generation:

- Who created it, and in what capacity? In employment context? Work for hire?
 - What are your institutional ownership policies for data (vs IP in general)? Do you need specific assignments?
- Does the data include or derive from any third party data or prior works?
- Any applicable sponsor or collaboration agreements?
- Right to collect, distribute/share, aggregate?

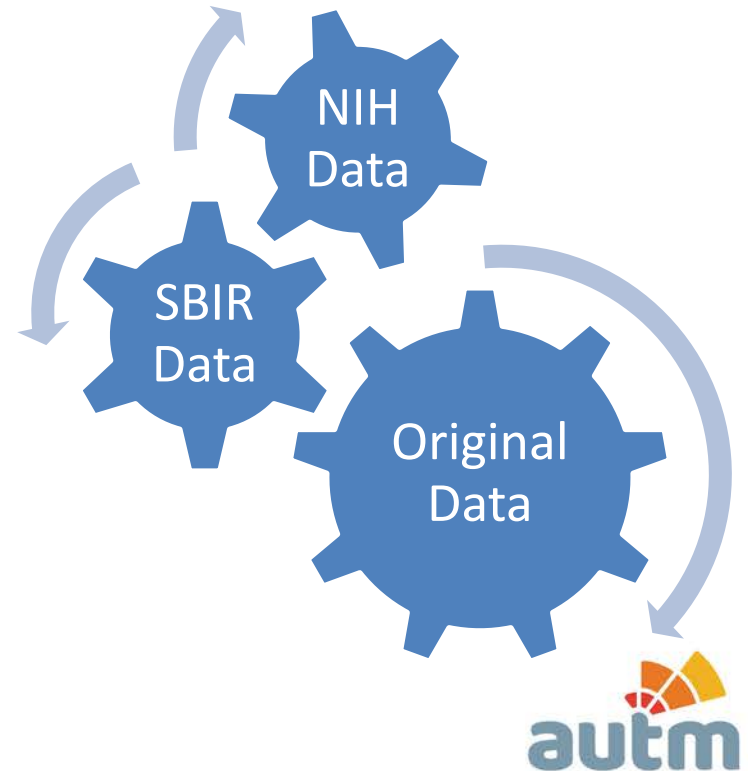
How Federal funding impacts data rights

- Difficulty in asserting an institution "owns" data from Federally-funded research
- Hard to promise "exclusivity" or confidentiality of Federally-funded data, given publication and sharing obligations
 - Check incorporated clauses and policies, plus grant application itself
- Data relating to subawards under private-company grants (like SBIR/STTR) can be subject to different rules



Data aggregations containing Federally funded data

- NIH, NSF, DOE, and others are given rights to data created/used in the work – this can encompass
 - Prior data; independent; third party
 - Software
- This can impact:
 - Reps/warranties of title
 - Ability to enforce against third parties (misappropriation?)
 - Obligations to third parties



How Privately Sponsored Research funding impacts data rights

Privately-funded SRAs create contractual obligations:

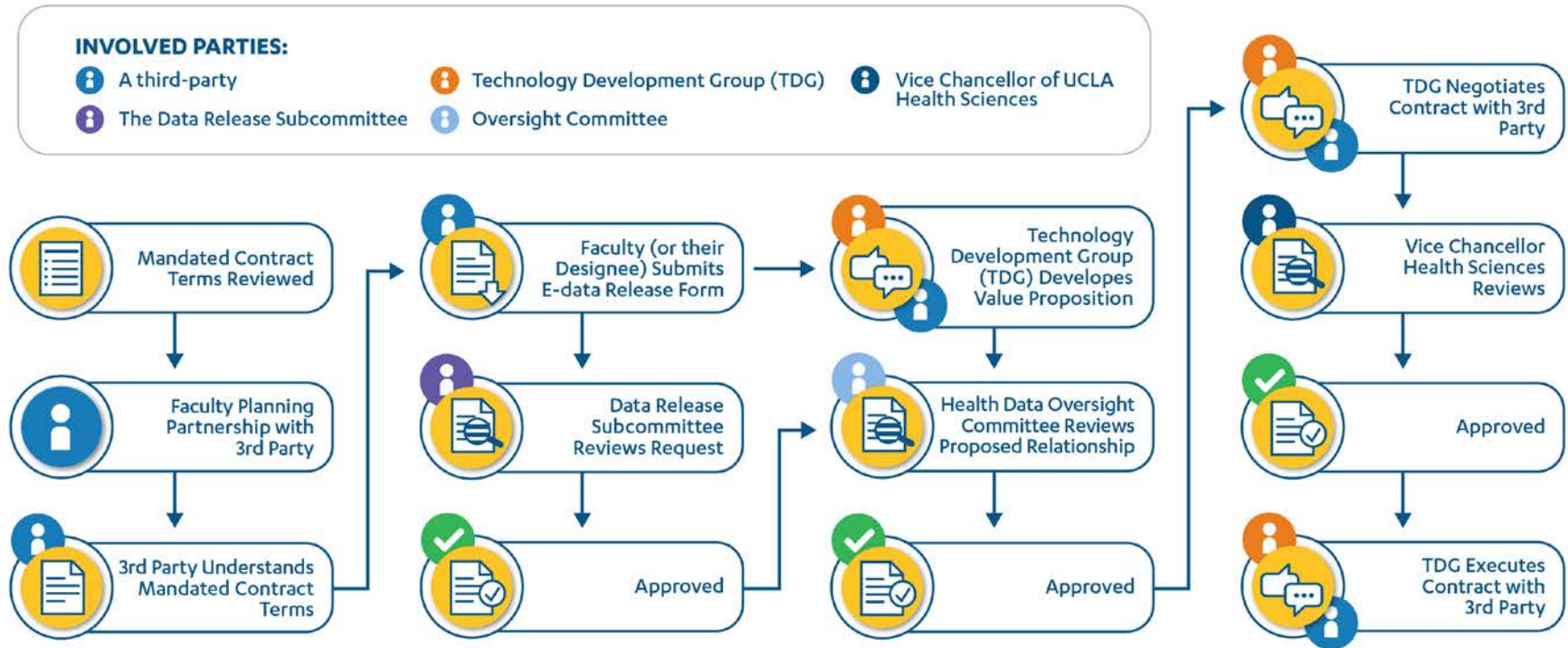
- Disclosure and reporting
 - New inventions "whether or not patentable"
 - Final reports
- Options and ROFNs
 - May involve reasonable disclosures of information
 - May extend to future improvements after end of SRA
- Often define ownership of "Results" and "Confidential Information"
- Distinction between SRA and Fee-for-Service

Once ownership is established, a few threshold Qs:

- ✓ **Stewards of the data – are they on board?**
- ✓ **Human data specific:**
 - Any consent, HIPAA, PHI/PII issues?
 - IRB consents to use the data sufficient for the intended purpose?
 - Heightened privacy and security concerns?
- ✓ **Conflicts of interest (actual or perceived)?**
- ✓ **Monetary consideration? If so, how much and distribution?**

Exemplary data release process:

Process Flow Diagram for Third Party Health Data Agreements Involving UCLA Faculty



Carefully define what you possess & license scope:

- Limit to *university's ownership interest* in the data
- Non-exclusive...exclusive...sublicense...transferability
- Right to use the “Results” or “Deliverables”
- Field of use – Research? Sell commercial products?
 - Consider being very specific = to provide Drug Screening Services
 - “Templates” should be used with caution

Define what you own with precision:

“**Associated Technology**” means University’s interest in non-patentable subject matter, including by way of example technical information, copyrightable works, processes, procedures, compositions, devices, tangible materials, methods, protocols, techniques, software, designs, drawings and/or data, that satisfies all of the following:

- (i) it exists as of the Effective Date of this Agreement,
- (ii) it was assigned to University by Prof. X, Y and Z pursuant to Case No. _____, and
- (iii) it is expressly identified in Appendix A of this Agreement.

For the avoidance of doubt, Associated Technology need not be, and University will have no obligation to keep Associated Technology, confidential or as a trade secret...

Example language – license grant:

License. Subject to the limitations and other terms and conditions set forth in this Agreement, University grants to Licensee a nonexclusive** license with respect to the Associated Technology to make, use, sell, offer for sale and import Licensed Products in the Field of Use.

**Caution on granting exclusive rights!

Perhaps unique circumstances would allow -- For a period of 1 year after the Effective Date, University's technology transfer office further agrees to not grant another commercial entity a license to the Associated Technology to sell Licensed Products in the Field of Use.

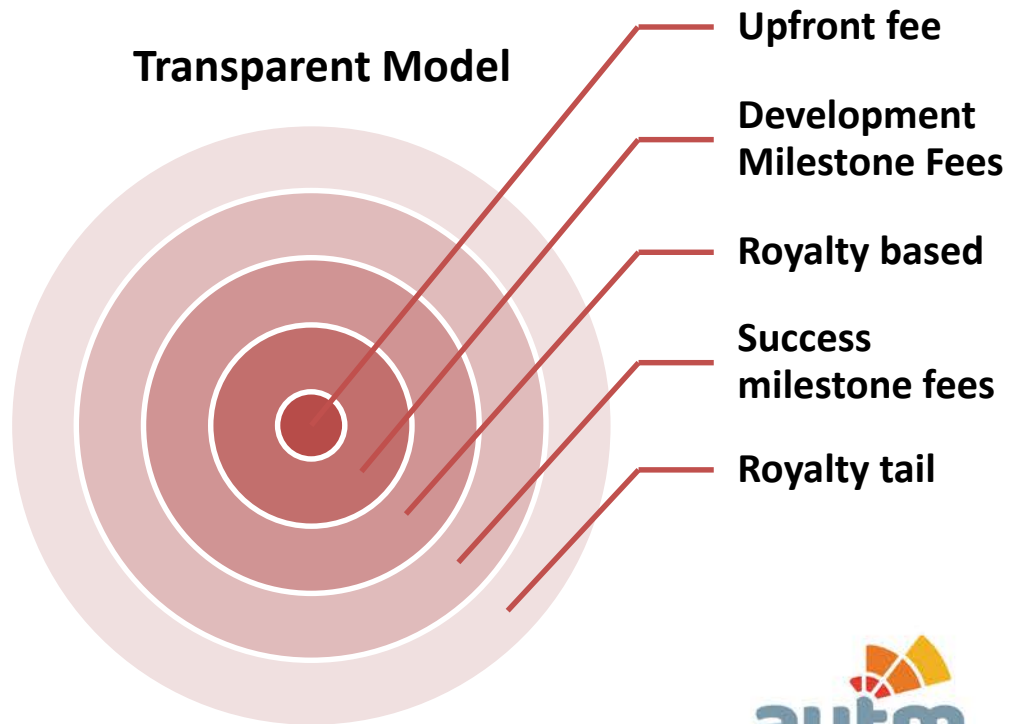
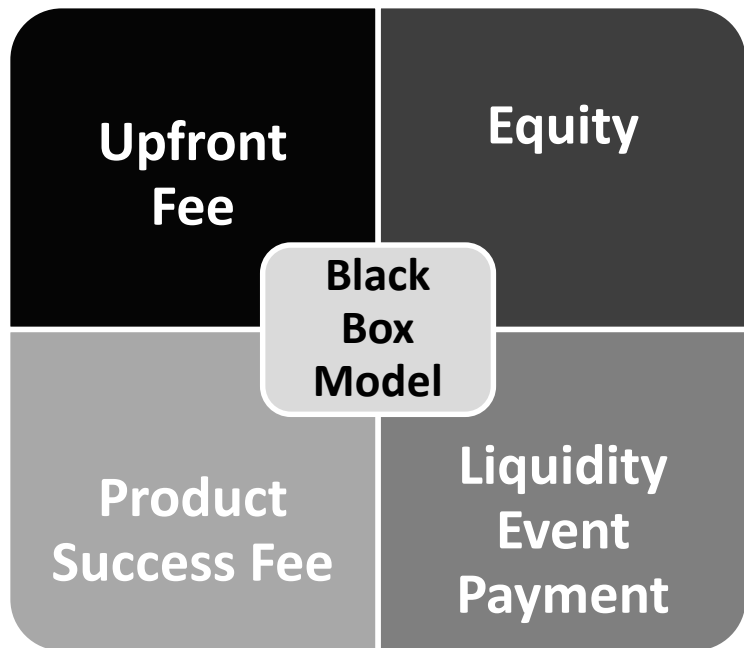


Example language - transfer and access restrictions:

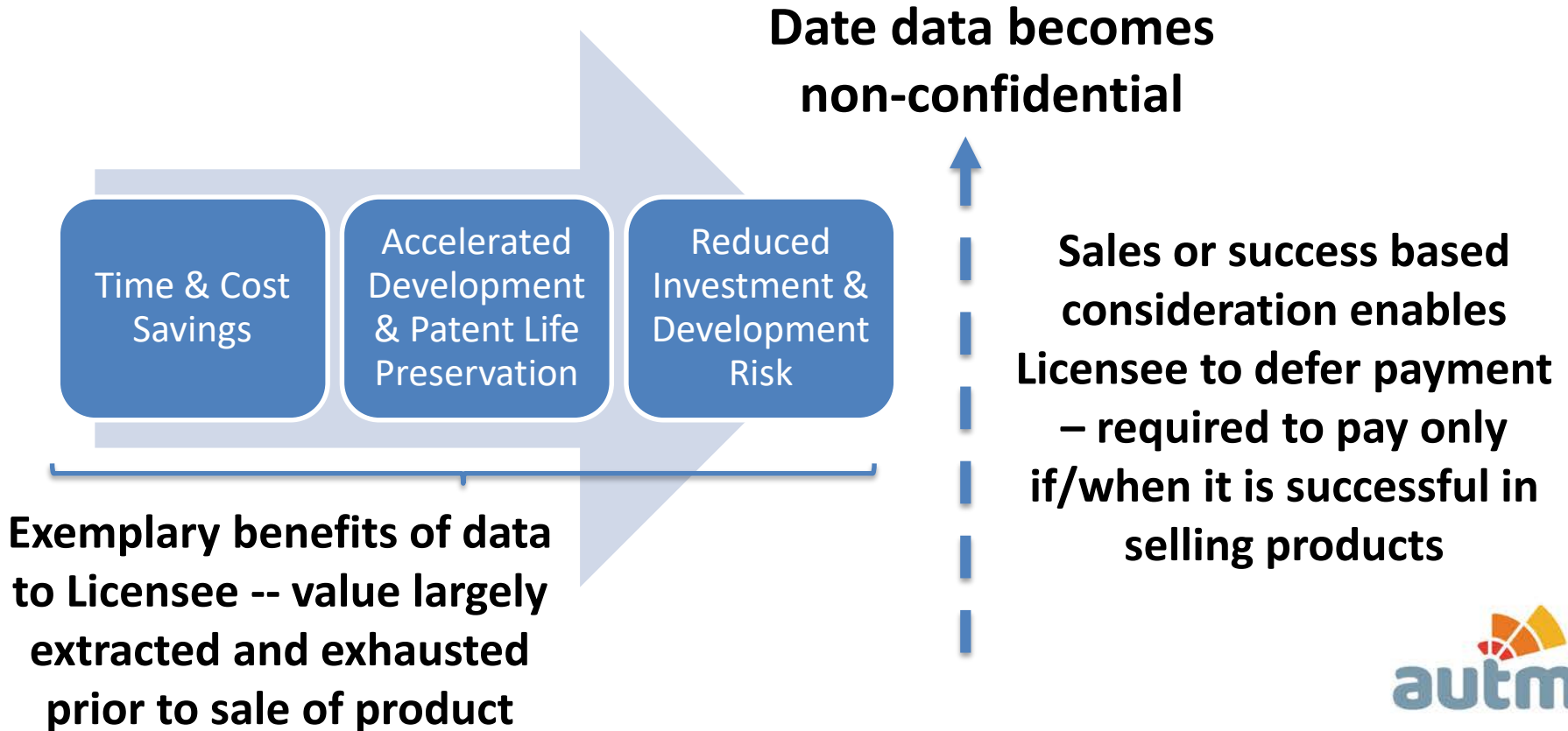
If the foregoing license grant includes the right to have access to any data that required campus approval (e.g., University IRB and/or data use committee), then such data may not be provided, sublicensed, assigned, transferred or in any other way provided to a third party without the prior express written consent of University.

Licensee has no right to, and shall not attempt to, identify the patient source of any data provided or licensed hereunder.

How to capture value? Ability to track is key.



“Why should I pay after data is in public domain?”



Example language – royalty-based tail:

1.5 “**Licensed Product**” means any product or service (i) whose manufacture, use, sale, offer for sale, importation, lease, disposition or provision would, absent the license granted hereunder, constitute infringement (including direct, contributory or inducement) of any Valid Claims of the Patent Rights or (ii) **developed, made or provided through the use of Associated Technology.**

This **royalty rate shall be reduced to X percent (X%) of Net Sales** with respect to Licensed Products that are **Licensed Products per Section 1.5(ii)**, but are not Licensed Products per Section 1.5(i).**

**Results in worldwide earned royalty obligation and royalty tail.



Royalty tail – be mindful of termination:

- **Issue = dynamics of data license are different from patent license**
 - less risk to licensee if you take the license away

This Agreement will remain in effect from the Effective Date until **X(X) years after the FCS of a Licensed Product in the U.S. or Europe with respect to the Associated Technology.**

Licensee may terminate its obligations under this Agreement with respect to Associated Technology only if it certifies in writing that it has destroyed and ceased all use of the Associated Technology, as well as any products or results incorporating and/or made through the use of the Associated Technology.

Example - milestone based consideration:

Associated Technology milestone payments. In consideration for the license granted to the Associated Technology under Section 2.1, Licensee will pay to University the following amounts within thirty (30) days of achieving such milestone – **Licensee's obligation under this Section 4.6 will survive termination of this Agreement:**

- A. First patient dosed with a Licensed Product in a Phase I trial: \$25,000
- B. First Commercial Sale of a Licensed Product in the US: \$50,000
- C. First Commercial Sale of a Licensed Product in a non-US country: \$50,000



Example – success fee:

Associated Technology Fee: Licensee must pay to University a milestone payment (the “Milestone Payment”) of X hundred thousand dollars (\$X00,000) within ninety (90) days of cumulative Net Sales first reaching Y million dollars (\$Y0,000,000) --

Licensee’s obligation under this Section 4.6 will survive termination of this Agreement. For purposes of clarity such Milestone Payment is due from Licensee irrespective of whether this milestone was reached by Licensee itself or a third party acting on Licensee’s behalf or by a Sublicensee, Joint Venture or Affiliate.



Example - Liquidity Event Payment:

Liquidity Milestone Payment. Within sixty (60) days of a Liquidity Event, Licensee shall make a cash milestone payment to University equal to X percent (X%) of P, provided that the X percent (X%) will step down by one quarter percent (0.25%) for every additional Y million dollars (\$Y,000,000) that Licensee receives from third parties as cash investment after the Effective Date, provided under no circumstances will such payment be reduced to less than Z percent (0.Z%) of P. This payment obligation will survive termination or expiration of this Agreement.

“P” means in the event of an IPO or Stock Sale, Licensee’s market capitalization calculated using the greatest per share price at which securities are sold in such IPO or Stock Sale; and in the event of a Merger or Asset Sale, the aggregate proceeds received and receivable by Licensee and/or its equity holders.



Example - Liquidity Event Payment (continued):

“**Liquidity Event**” means the sooner of (a) the closing of an initial public offering of Licensee’s securities (“**IPO**”), (b) the closing of any consolidation, merger or other transaction(s) of Licensee (or any subsidiary of Licensee, if a subsidiary is a constituent party and Licensee issues securities pursuant to such transaction), in which greater than fifty-one percent (51%) of Licensee’s (or such subsidiary’s) voting power is transferred to a third party (“**Merger**”), (c) the sale by one or more security holders of securities representing at least fifty-one percent (51%) of the voting power of Licensee (“**Stock Sale**”), or (d) sale by Licensee of all or substantially all of its assets (“**Asset Sale**”).

The value of any non-cash proceeds shall be determined in good faith by Licensee’s board, taking into account any value attributed to such consideration by the transacting parties and recent third party valuations. If such non-cash proceeds are in the form of publicly-traded equities, their value shall instead be the average closing price of such equities over the thirty (30) days prior to the closing of the Liquidity Event.



Don't forget about liability:

Indemnification & Insurance: consider including cyber insurance requirement, e.g., *“cyber-insurance policy to insure its reasonable costs in investigating and responding to a cyber-incident or Breach with a limit of \$1,000,000 per occurrence and \$2,000,000 in the aggregate.”*

Disclaimer of Warranties: consider expressly placing Licensee on notice that the dataset could include third party rights and that it is Licensee's sole obligation to determine what rights it needs.

Limitation of Liability: consider the nature of what you are licensing and whether you need to address the potential for security breaches, third party claims to ownership, etc.

Confidentiality: consider whether to lengthen the duration of the obligation



THANK YOU!

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