



We will begin momentarily at 2pm ET



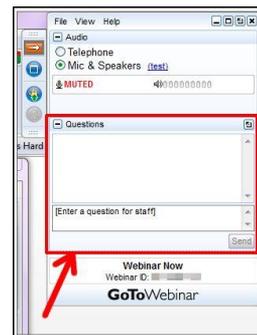
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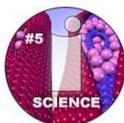
- Know your career options
- Develop strategies to strengthen your skills
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Advances in Graphene Nanotechnology: Making the Paralyzed Walk

Thursday, June 1 @ 2-3pm ET
 Part five of the 2017 Industrial Science Series



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completely severed in two. This recent discovery has important implications for those with spinal cord injuries that have induced paralysis.

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What You Will Learn

- How to make rats recover from spinal cord scission using advanced materials and the implications for humans
- Why this treatment works and is so effective in current studies
- What led us into this research and story behind the discovery

Experts



James Tour
 Rice University

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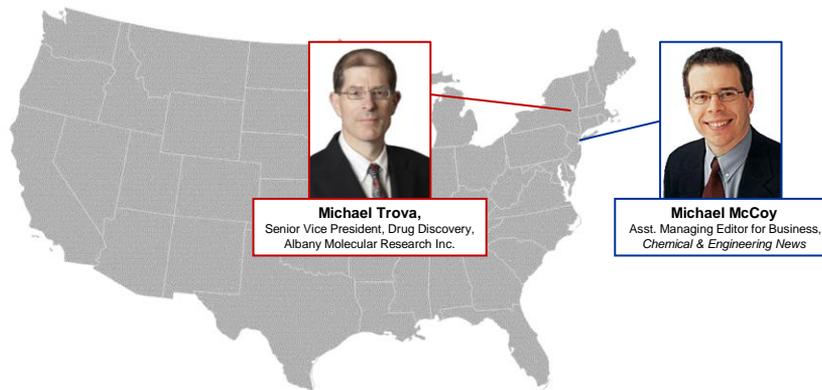
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"Insourcing and Outsourcing in R&D: Trends in the Pharma Industry" Session 4 of the 2017 Industry Science Series



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ACS Webinar Series

Insourcing and Outsourcing in R&D: Trends in the Pharma Industry

Michael P. Trova, Ph.D.
May 4, 2017

Today, You Will Learn:

- Definition of an insourcing model and how it differs from a traditional outsourcing relationship
- Key attributes of a qualified CRO/CDMO insourcing and outsourcing partner
- Trends in insourcing and outsourcing drug discovery services



Definition

- **CRO/CDMO**

- Contract Research Organization / Contract Development Manufacturing Organization
- Provides products and/or services to Life Sciences and Agricultural companies on a contract basis
- Services can include: Discovery, Development, Manufacturing
- Services can be Outsourced or Insourced to the CRO/CDMO
- *CRO distinct in this presentation from Clinical Research Organizations (CROs)*

- **Customer**

- Organization that requires services from CRO/CDMO

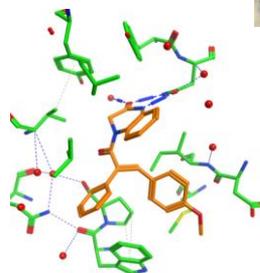


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Why do companies Outsource / Insource?

- Capacity shortfall
- Capability / expertise / labor gap
- Customer can focus on core expertise
- Resource flexibility
- Cost control
- Market access / market intelligence



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Insourcing – What is it?

New sourcing solution for pharma/biotech that delivers an ideal combination of quality, productivity and cost-efficiency.

- CRO/CDMO work on-site at customer location, in an integrated fashion
- Work conducted in “real time” with customer teams
- Outstanding performance and cycle time delivery
- Highly cost competitive on the global market



Outsourced vs. Insourced Services – Similarities and Differences

	Outsource	Insource
Activity	Discovery, Development, Manufacturing	Discovery, Development, Manufacturing
Staffing	CRO/CDMO's employees	CRO/CDMO's employees
Location of service	CRO/CDMO's facilities	Customer's facilities
Communication & Problem solving	Site visits Teleconference, videoconference, secure portals Time zone consideration	Face-to-face on-location - in real time Use customer IT infrastructure (ELN, LIMS, Databases, search engines) No time zone issues
Intellectual property control	CRO/CDMO dependent	Excellent control
Reagent procurement	CRO/CDMO's network and negotiated rates	Customer's network and negotiated rates
Cycle times	Shipping needed, time zone considerations, customs	Instantaneous, usually little shipping needed
Cost	Competitive	Less per FTE than equivalent outsourcing



Insourcing – Important Considerations

CRO/CDMO “on-site” with access to Customer’s facility and information

- Customer HR and Legal framework defines accountabilities
- Mitigate with security access and IT restrictions
- Select CRO/CDMO with Expertise and Values similar to Customer
- Monitor and course correct as needed

These considerations can be managed in the partnership!



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Insourcing – Real-time benefits

Insourcing also offers the following “unexpected” benefits:

- CRO/CDMO use underutilized customer resources
- Develop interpersonal relationships between customer and CRO/CDMO
 - Build trust and teamwork
 - Sense of community = greater commitment to purpose
- CRO/CDMO manages all insource activity
 - Employee recruitment and training
 - Employee relation / engagement / retention
 - Project and performance management
 - Customer defines scope of work – not “how” its done
- EHS, licenses, accreditation compliance ensured



Significant savings on an FTE cost basis



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Audience Trivia Question # 1:

Which one of the following attributes is important in a CRO Insource/Customer partnership? (There may be more than one correct answer)

- Leadership team alignment
- CRO expert in subject matter
- Trust between the partners
- None of the above

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Selecting Your Insourcing Partner Ideal Characteristics

- CRO/CDMO and Customer must share similar **Core Values**
- Leadership teams aligned in expectations and execution
 - Onsite CRO/CDMO leadership important for success
- CRO/CDMO must be **known expert in subject matter**
 - Customer should not train subject matter to the CRO/CDMO
 - Expertise in the business model added benefit
- Remain Flexible. Think creatively. **One size does NOT fit all!**
- Customer must be able to implicitly **Trust** the CRO/CDMO



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Insourcing – Variations on a Theme

- **Start-up Insource Structure**
 - CRO/CDMO hire majority of staff from market
 - Seed the team with seasoned CRO/CDMO staff
- **Take-over existing staff structure**
 - CRO/CDMO hire existing staff as CRO/CDMO employees
 - Put organizational structure in place
 - Stability, benefits, career development, etc.
- **Combination of above**
- **Models can be highly flexible**



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Customer Testimonial Feedback:

Did the Insourcing activity implemented meet Customer expectations?

“...reduction of geographic and IP risk achieved...”

“...[customer employees allowed to spend] more ‘high value activity’ time...”

“...cycle times significantly reduced & enabled real time lab level decision making...”

“...observed increased control on critical processes, and reduced overhead costs...”

“...overall value is at least equal to, if not better than, outsourcing...”



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Selecting Your Sourcing CRO/CDMO Partner

- Qualified staff with relevant expertise
- Identify and solve technical problems
- Excellent communication skills
- Offer cutting edge technologies and expertise
- Integrated services – Discovery, Development, Manufacturing
- Provide quality, reliability and productivity
- Provide Value at competitive rates



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Trends in Insourcing and Outsourcing Discovery Services

Audience Trivia Question # 2:

What is the estimated total global R&D spend made by the biopharmaceutical industry in 2016?

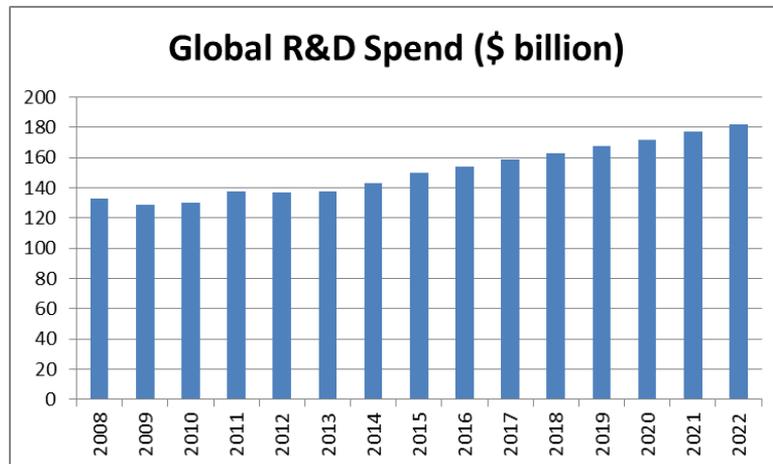
- \$ 20 Billion
- \$ 50 Billion
- \$ 150 Billion
- \$ 200 Billion
- \$ 225 Billion

¹Source: The Statistics Portal, "Total Global Pharmaceutical Research and Development (R&D) Spending from 2008 to 2022 (in billion US dollars). <https://www.statista.com/statistics/309466/>

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Global Annual R&D Spend (\$ billion) in the Biopharmaceutical Industry



¹Source: The Statistics Portal, "Total Global Pharmaceutical Research and Development (R&D) Spending from 2008 to 2022 (in billion US dollars). <https://www.statista.com/statistics/309466/>

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Venture Funding in Drug Discovery: Geographic Trends

- Boston and San Francisco received approximately 70% of VC funding in 2016¹

- Areas with the top funding deals¹

1. Northern California
2. Massachusetts
3. Southern California
4. New York
5. Canada
6. UK



- Vancouver, BC is fast becoming a biotech innovation hub
 - ex. US\$500 million venture fund was created in 2016 based out of Vancouver²

¹Source: Silicon Valley Bank, *Trends in Healthcare Investments and Exits 2017*

²Source: Pratt, Chelsea. "\$500M Biotech Venture Fund to Be Based in Vancouver." *Biotech Investing News*, Oct. 18, 2016



Audience Trivia Question # 3:

How much has the average global human life expectancy increased in the last ca. 140 years?

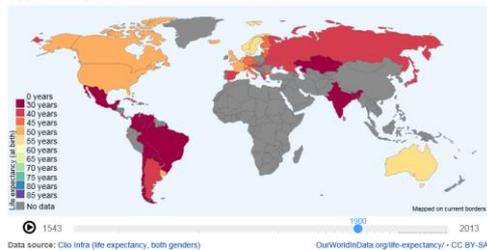
- 30 years
- 40 years
- 50 years
- 60 years
- 70 years

Source: <https://ourworldindata.org/life-expectancy/>



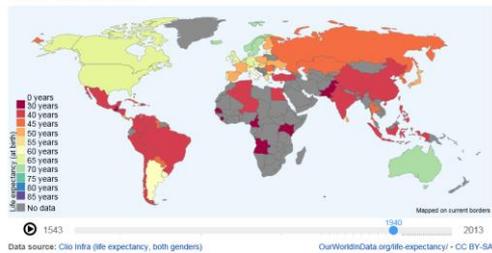
Life expectancy, 1900

Life expectancy at birth is the average number of years a child born would live if current mortality patterns were to stay the same.



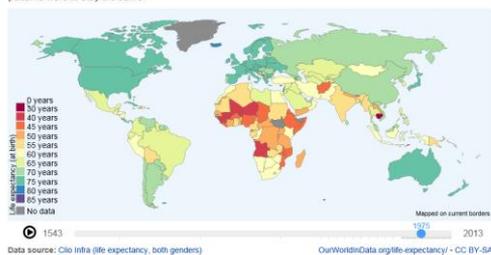
Life expectancy, 1940

Life expectancy at birth is the average number of years a child born would live if current mortality patterns were to stay the same.



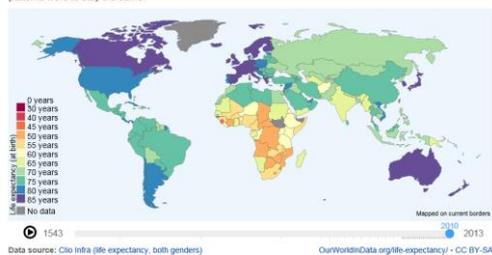
Life expectancy, 1975

Life expectancy at birth is the average number of years a child born would live if current mortality patterns were to stay the same.



Life expectancy, 2010

Life expectancy at birth is the average number of years a child born would live if current mortality patterns were to stay the same.



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Source: <https://ourworldindata.org/life-expectancy/>



Major Unmet Needs in Healthcare

Oncology:

- Numerous cancers remain terminal

CNS Diseases:

- Alzheimer's Disease
- Dementia
- Mental health disorders

Orphan/Rare Diseases:

- Huntington's Disease
- Cystic Fibrosis
- Many others

Infectious Diseases:

- Viral infections
- Bacterial infections
- Tropical diseases



There remain many diseases that are still untreatable, and many more we don't even know about.



Discovery Market: Trends and Observations

- Venture **investment** in and **partnering** opportunities are **increasing**
- Government funding **targeting translational discovery/development** of therapies
- **Outsourcing** of early drug discovery research is **increasing**
 - Early companies who are cap-ex limited
 - Can't reduce great ideas to practice
- Consolidation of CRO/CDMO's – move to preferred / long-term strategic partnerships



Discovery Outsourcing Trends: Pharma versus Biotech

Pharma:

- Preferred providers and strategic partnerships
- Early stage screening
- High potency work
- Library generation
- Biology services
- Medicinal and analytical chemistry
- Molecular pharmacology

Biotech:

- Interested in growing pipeline of biologics
- Early stage screening
- HTS systems that range from semi automated to fully automated robotic systems to increase productivity
- Biology services
- Medicinal and analytical chemistry
- Molecular pharmacology



Audience Trivia Question # 4:

We already stated that the Global R&D spend in 2016 is ca. \$150 Billion. **How much of that spend is estimated to be spent on Discovery Outsourcing in 2016?**

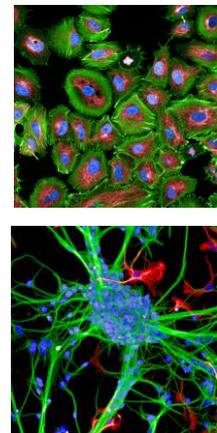
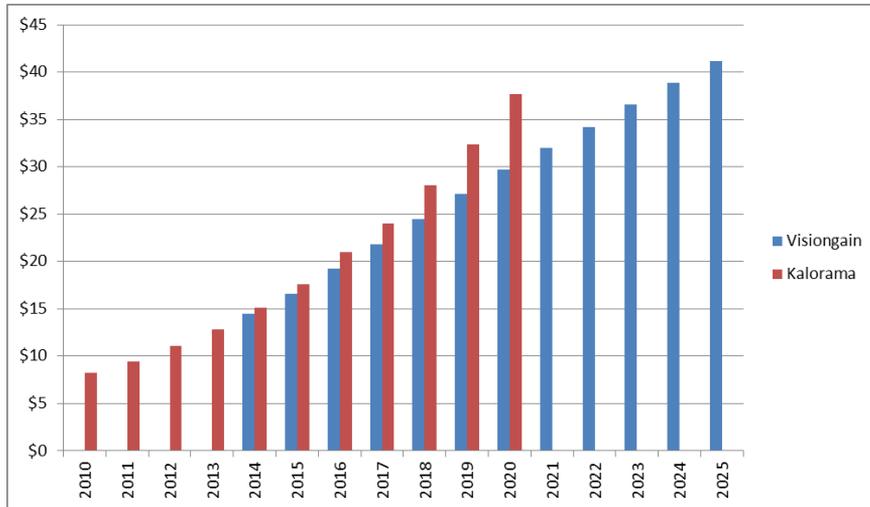
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- \$ 40 Billion
- \$ 50 Billion

¹Source: Visiongain, "Drug Discovery Outsourcing Market Forecast 2015-2015, Opportunities for Leading Companies," 2016.
²Source: Kalorama Information, "Outsourcing in Drug Discovery," April 2016.

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Global Annual Discovery Outsourcing Market Revenue Forecast (\$ billion)



¹Source: Visiongain, "Drug Discovery Outsourcing Market Forecast 2015-2015, Opportunities for Leading Companies," 2016.
²Source: Kalorama Information, "Outsourcing in Drug Discovery," April 2016.

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Segment Revenue Analysis for Discovery Outsourcing in 2016 (ca. \$20.7 billion)

High Throughput Screening (6%):

- Assay development
- Assay production
- Robotic activities

Biology Services (32%):

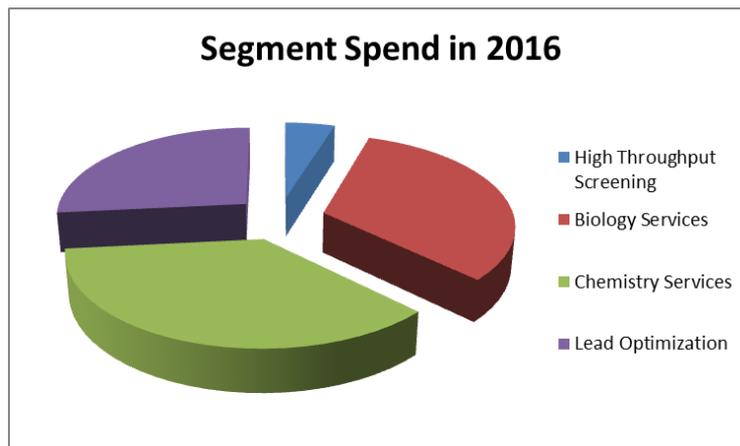
- Target identification
- Protein production
- In vitro screening/testing

Chemistry Services (36%):

- Library synthesis
- Medicinal chemistry
- Reference standards

Lead Optimization (26%):

- Medicinal chemistry
- In vitro pharmacology
- In vivo pharmacology
- In vivo ADME/Tox evaluation

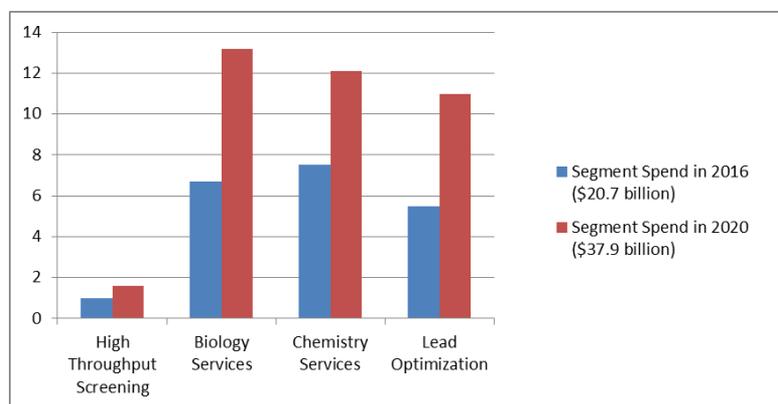


Source: Kalorama Information, "Outsourcing in Drug Discovery," April 2016.



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Annual Segment Revenue Trends for Discovery Outsourcing in 2016 - 2020



	% of Total Spend 2016	% of Total Spend 2020
High Throughput Screening	6	4
Biology Services	32	35
Chemistry Services	36	32
Lead Optimization	26	29

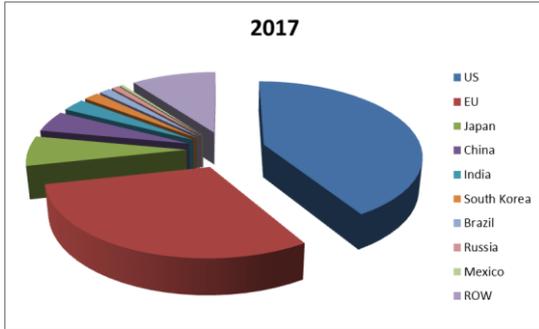


Source: Kalorama Information, "Outsourcing in Drug Discovery," April 2016.



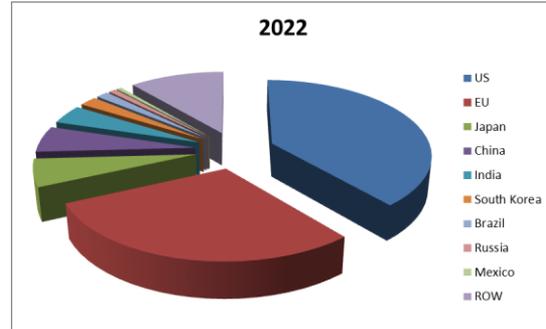
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Discovery R&D Outsource Market by Country 2017-2022



Total outsource spend 2017: \$ 21.8 billion

US: 41%
EU: 30%
Japan: 6.4%



Total outsource spend 2022: \$ 34.2 billion

US: 38.5%
EU: 29%
Japan: 5.8%

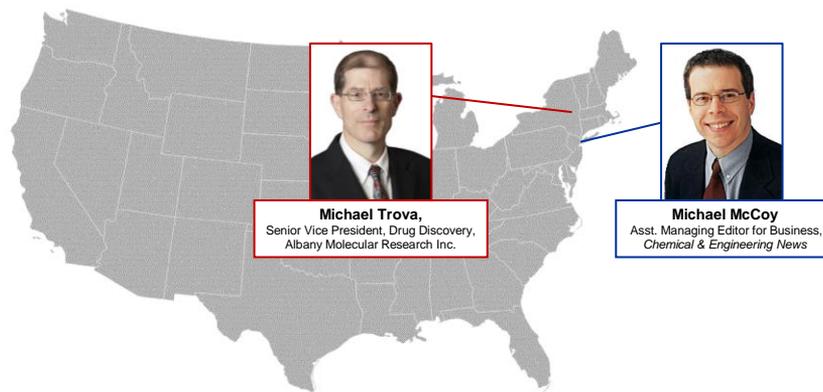
¹Source: Visiongain, "Drug Discovery Outsourcing Market Forecast 2015-2015, Opportunities for Leading Companies," 2016.
EU = UK, France, Germany, Spain & Italy

Take Home Message

Externalization of R&D for the pharmaceutical and biotechnology industries is mainstream today; successful application of Insource and Outsource strategies is critical to the success of R&D pipelines of the future.



“Insourcing and Outsourcing in R&D: Trends in the Pharma Industry”
Session 4 of the 2017 Industry Science Series



Michael Trova,
Senior Vice President, Drug Discovery,
Albany Molecular Research Inc.

Michael McCoy
Asst. Managing Editor for Business,
Chemical & Engineering News

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- What led us into this research and story behind the discovery

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James Tour
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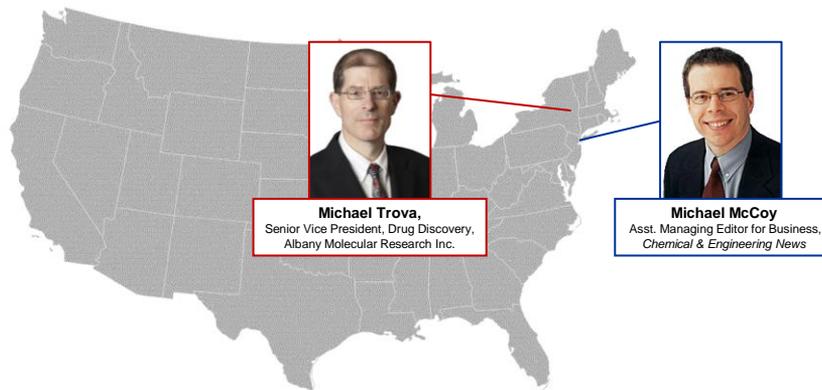
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