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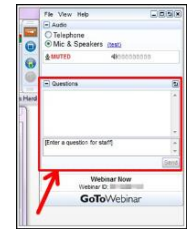

Type them into questions box!

"Why am I muted?"
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Kyla Hoggins
Student, Skagit Valley College

https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/car-t.html

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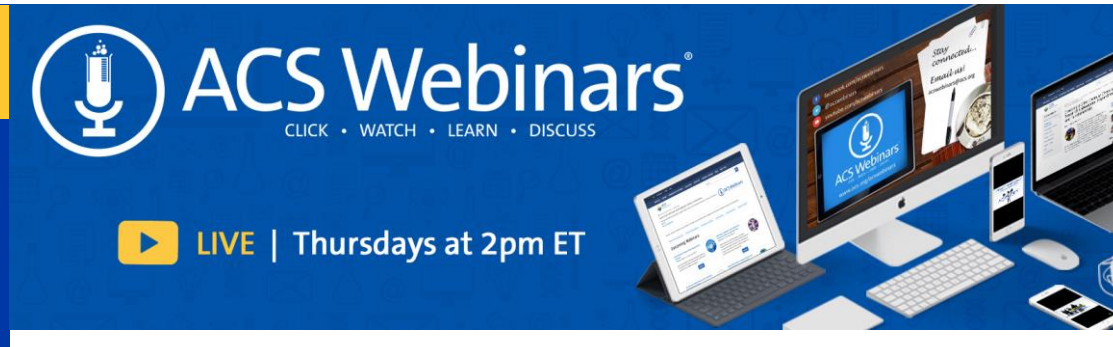

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ACS Heroes of Chemistry Award

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2018 Winners: AstraZeneca, DuPont, Pfizer, SeattleGenetics

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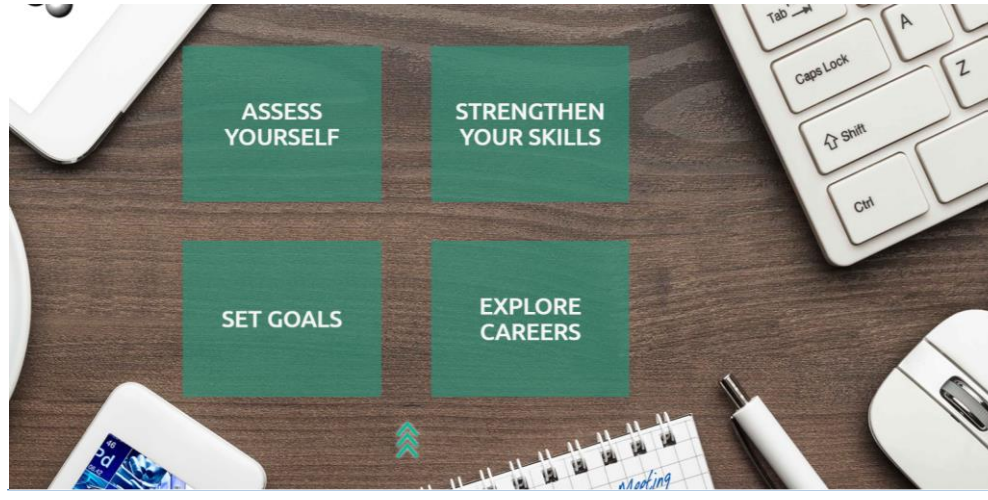
An individual development planning tool for you!



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Upcoming ACS Webinar!

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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019

Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework, careful planning of timing and projected costs to secure needed regulatory approvals is essential.

What You Will Learn

- Working with gene editing technology poses unique intellectual property and regulatory challenges, from the R&D discovery through post-launch phases of the product development lifecycle
- The current regulatory framework is product specific, currently morphing and complicated by global trade issues
- To be most effective, intellectual property strategy needs to be tied to business goals, and focused on developing offensive and defensive positions beyond the traditional "is it patentable" lens

EXPERTS

Cassie Edgar
McKee, Voorhees & Sease

Jonathan Kennedy
McKee, Voorhees & Sease

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https://www.acs.org/content/acs/en/acs-webinars/business-entrepreneurship/gene-editing.html

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Upcoming ACS Webinar

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ACS Chemistry for Life®

Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research

Drug Design and Delivery Series | September 19, 2019

Over the past 50 years, crop protection has evolved from using pesticides in high use rate to applying safer, selective, and more efficacious products, which share many of the features of modern drugs. Resistance development and environmental concerns are key drivers in the search for new, improved agrochemicals, which are currently discovered and optimized following a complex and demanding path similar to that followed in drug discovery.

Join Fides Benfatti of Syngenta Crop Protection during this free interactive broadcast as she demonstrates through various case studies much like Drug Discovery, crop protection research is a daunting challenge that has to be faced with world-class science where both industries can gain valuable insight from each other.

EXPERTS

Fides Benfatti
Syngenta Crop Protection

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aaps
American Association of Pharmaceutical Scientists

What You Will Learn

- What are the challenges to identify safe, selective, and efficacious agrochemicals
- How these challenges are addressed, revealed through case studies
- Similarities and differences between crop protection and pharmaceutical research

https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/compound-designs.html

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aaps American Association of Pharmaceutical Scientists

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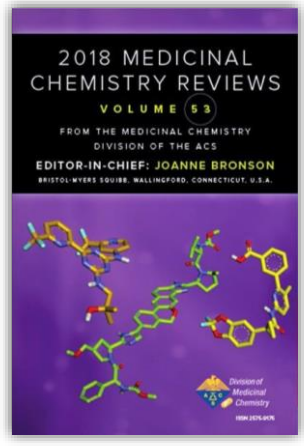

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Celebrating 5 years & 50 Drug Discovery Webinars!

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2019 Drug Design and Delivery Symposium

http://bit.ly/2019DDDS

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Jan 31	**How to Succeed in Drug Discovery: Insight from Medicinal Chemists** (1.5 hrs.)	John Lowe III - JL3 Pharm Mark Murcko - Relay Therapeutics Ann Weber - Kallyope William Greenlee - MedChem Discovery Consulting
Feb 28	**Cosolvent Molecular Dynamics: Mapping Protein Surfaces to Discover Allosteric Sites**	Heather Carlson - University of Michigan Rommie Amaro - UC San Diego
Mar 28	**Women at the Interface of Computational Chemistry and Drug Discovery** (1.5 hrs)	Zoe Cournia - Biomedical Research Foundation and *JCIM* Kate Holloway - Gfree Bio Yvonne C. Martin - Previously of Abbott Laboratories Shana Posy - Bristol-Myers Squibb
Apr 18	**Effective Exploration of Chemical Space in Hit-Finding**	Hanneke Jansen - Novartis Institutes for BioMedical Research Zoe Cournia - Biomedical Research Foundation and *JCIM*
May 30	**Widening the Therapeutic Window: Kinetic Selectivity and Target Vulnerability**	Peter Tonge - Stony Brook University and *ACS Infectious Diseases* Stewart Fisher - C4 Therapeutics
Jun 27	**Precision Control of CRISPR-Cas9**	Amit Choudhary - Broad Institute of Harvard and MIT Venkat Krishnamurthy - AstraZeneca
Aug 8	**Transformation of Recombinant Cells to FDA Approved Products: Clinical Development to Marketplace** (New Date)	Rodney Ho - University of Washington Venkat Krishnamurthy - AstraZeneca
Aug 22	**The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models**	Bart DeCorte - MercachemSyncom Allen Reitz - Fox Chase Chemical Diversity Center
Sep 19	**Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research**	Fides Benfatti - Syngenta
Oct 24	**Treating Diabetes: Designing the Once-Weekly and Oral GLP-1 Semaglutide**	Jesper Lau - Novo Nordisk A/S
Nov 28	**Prodrugs**	Jarkko Rautio - University of Eastern Finland

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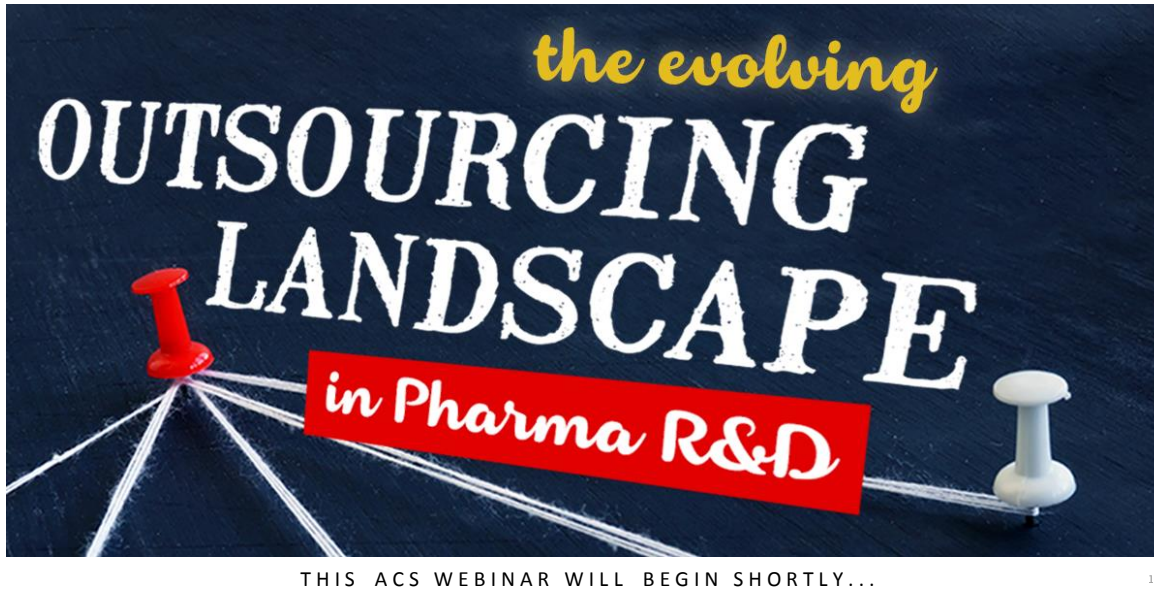

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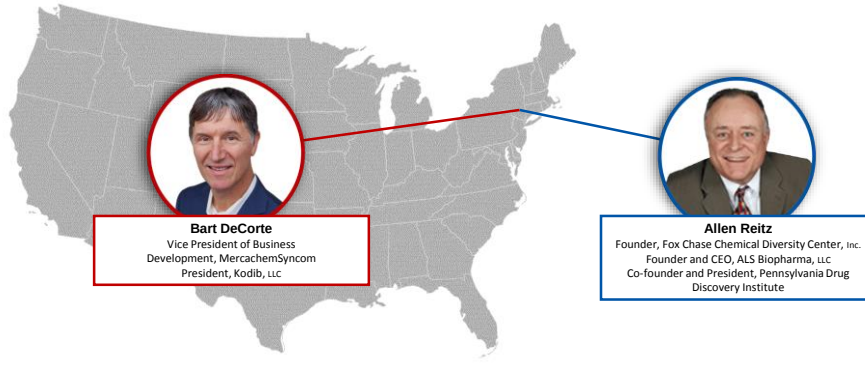
ACS Chemistry for Life®

The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models



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Vice President of Business Development, MercachemSyncom
President, Kodib, LLC

Allen Reitz
Founder, Fox Chase Chemical Diversity Center, Inc.
Founder and CEO, ALS Biopharma, LLC
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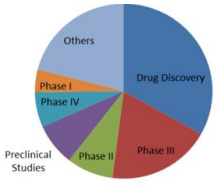
Overview



- Outsourcing by the numbers
- Evolution of the pharma R&D model
- Outsourcing models
- Pros and cons of different models
- Factors to consider when choosing a CRO

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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

My organization…

- Is a client that partners with CROs to execute its drug discovery programs
- Is a CRO that provides specialized services (chemistry, biology, etc.)
- Is a CRO that provides integrated services (combination of chemistry, biology, eADME and in vivo pharmacology services)
- Question not applicable to me

** If your answer differs greatly from the choices above tell us in the chat!*

Outsourcing by the Numbers

GRAND VIEW RESEARCH

The **global healthcare contract research organization market** size is expected to reach **USD 54.7 billion by 2025** with an expected CAGR of 6.6% [1]

visiongain

The **global drug discovery outsourcing market** was expected to reach **$22.69 bn in 2018**, dominated by the chemistry services segment. Expected to grow at a CAGR of 11.7% between 2018 and 2023 [2]

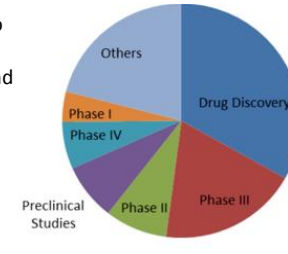
The Business Research Company

The **CRO market** is expected to reach **$44.4 billion in 2021** and is forecasted to grow 12% year-on-year through 2021 [3]

VANTAGE
Fast Track Results. High Performance Teams.

Over **80% of biopharma** respondents report **increased alliance activity** compared to 5 years ago [4]

Contract Research Services Market Segment Shares (%)

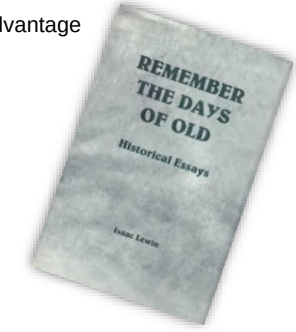


[1] https://www.grandviewresearch.com/press-release/global-healthcare-cro-market
[2] https://www.visiongain.com/report/global-drug-discovery-outsourcing-market-forecast-to-2028/
[3] https://www.outsourcing-pharma.com/Article/2018/05/03/CRO-market-to-reach-44.4bn-by-2021?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright
[4] https://www.vantagepartners.com/insights/the-perils-and-promise-of-strategic-partnering-with-cros/

The Days of Old – Dominated by Big Pharma

Drug Discovery Model:

- Long-term commitment to specific therapeutic/disease areas
- Internal scientists are considered world-leading experts – key to competitive advantage
- 'Not invented here syndrome'
- Occasional relationships with top academic institutions
  - No strings attached
  - Little or no alignment with internal priorities
  - Publications



Execution:

All aspects of the drug discovery process are executed internally

- Chemistry
- Vivo pharmacology
- Process R&D
- Vitro biology
- Toxicology
- Clinical Development

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The Turbulent 2000's

Major transformation of how pharma executes drug discovery:

- Significant head count reductions in internal drug discovery and development
- Search for cheaper ways to execute science

Drivers:

- Increased cost of R&D
- Patent expirations
- Unrealized benefits from consolidations
- Increased regulatory pressures
- Reimbursement

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Need for More Cost-Effective Execution

First phase: Clinical activities

- Need for global clinical research network

Second phase: Chemical development activities

- Sourcing of building blocks
- Assembly of intermediates (non-GMP)
- GMP production

Third phase: Drug discovery activities

- Dramatic shift of resources to lower cost countries to perform 'routine science'
- Capital efficiency: fixed costs become variable costs
- Capital flexibility: resources and spending can be adjusted rapidly

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Increased Complexity of Drug Discovery

Chemistry:

- Fragments
- *In silico* libraries
- Flow chemistry
- Chiral technologies
- DNA-encoded libraries
- PROTACS

Biology:

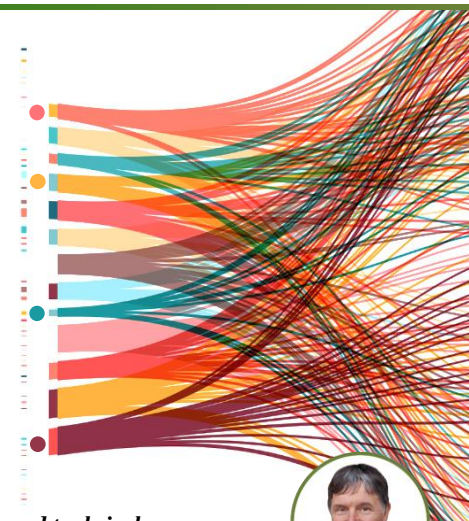
- Molecular targets
- Protein production
- Screening platforms
- High content screens
- Omics

Biophysical techniques:

- X-ray
- Cryo EM
- NMR
- Etc.

Big Data and AI:

- Novel targets
- Coupling of gene expression data with clinical data
- Etc.



No organization has the resources to bring all the expertise and tools in-house.

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Relocation / Redistribution of Risk

- Recruit external investment in drug discovery process
- Let biotech companies and venture capital take on most of the risk
- Large pharma companies more and more become drug development and marketing machines
- Some of the CROs now are major investors in venture funds

In the past 20 years, the industry went from

not invented here syndrome…

to

… the world is our laboratory

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Audience Survey Question

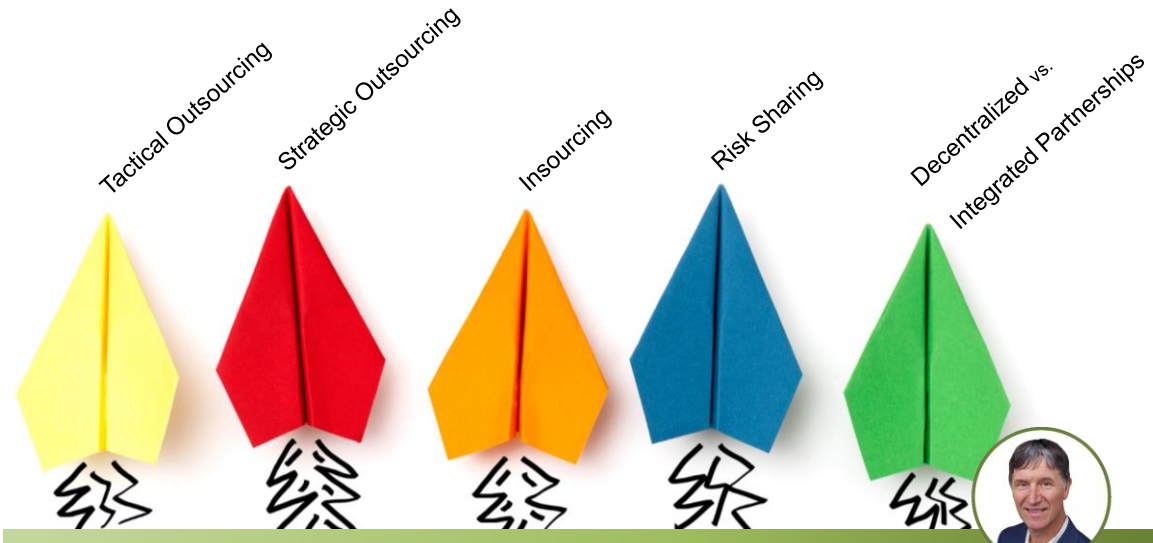
ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

To what extent does your organization rely on CRO partnerships?

- We do not work with CROs to execute our drug discovery programs
- We use CROs for less than 1/3 of our drug discovery programs
- We use CROs for 1/3 to 2/3 of our drug discovery programs
- We use CROs for more than 2/3 of our drug discovery programs
- My organization is a provider of services

** If your answer differs greatly from the choices above tell us in the chat!*

Outsourcing Models



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Tactical Outsourcing Model

- Typically short-term in nature
- Focused more on delivering a specific service as opposed to a value-added service
- Convenient way to expand capacity when internal resources are limited
- Often motivated by need to manage peak work volume and to accelerate completion of projects more quickly

Often based on fee-for-service (FFS) arrangements

Risk lies mostly with CRO

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Strategic Outsourcing Model

- Often based on blend of in-house and external resources
- Expectation of added value contributions
- Prioritizes longer term collaborative partnerships over short term project tasks
- Goal: establish reliable external partnerships

Often based on Full Time Equivalent (FTE) arrangements

Shared risk

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Insourcing Model

- Less common
- Mostly limited to large pharma organizations
- Frequently driven by excess real estate

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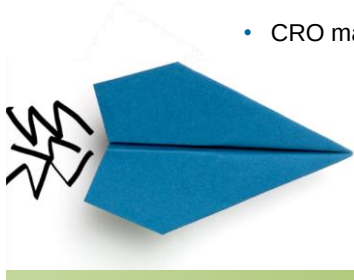
Risk Sharing Partnerships

- Project can originate at CRO or at pharma organization
- Milestone and possibly royalty payments
- IP can be shared or fully transferred to pharma organization
- CRO may agree to lower FTE (full time equivalent) rate or offer in-kind services



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Audience Survey Question

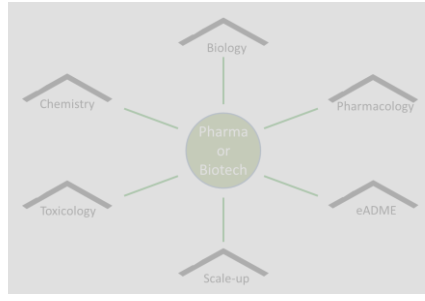
ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

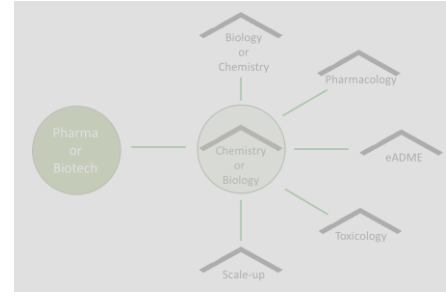
My organization's relationships with CROs are mostly based on:

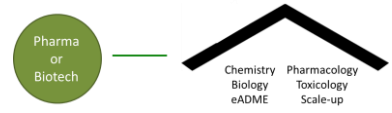
- FFS (fee-for-service) based agreements
- FTE (full time equivalent) based agreements
- A mixture of both FFS and FTE agreements
- Risk sharing agreements
- Question not applicable to me

** If your answer differs greatly from the choices above tell us in the chat!*

Decentralized vs. Integrated Partnerships







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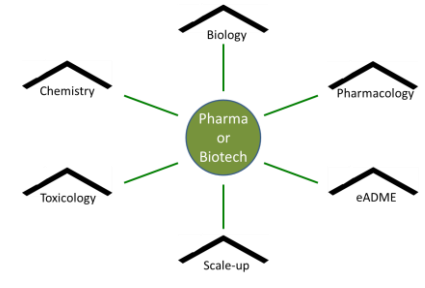
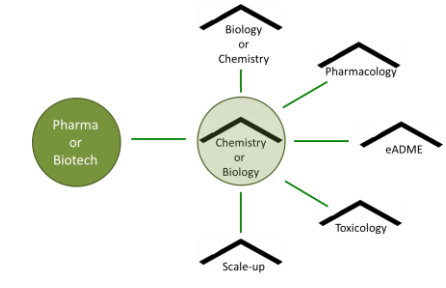
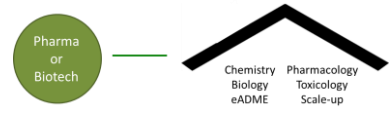
Decentralized vs Integrated Partnerships







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Factors to Consider when Choosing a CRO

- Cost
- IP considerations
- Academic/industrial
- Data sharing and data integrity
- Safety and personnel policies
- Problem Solving skills
- Communication
- Turnover

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Cost

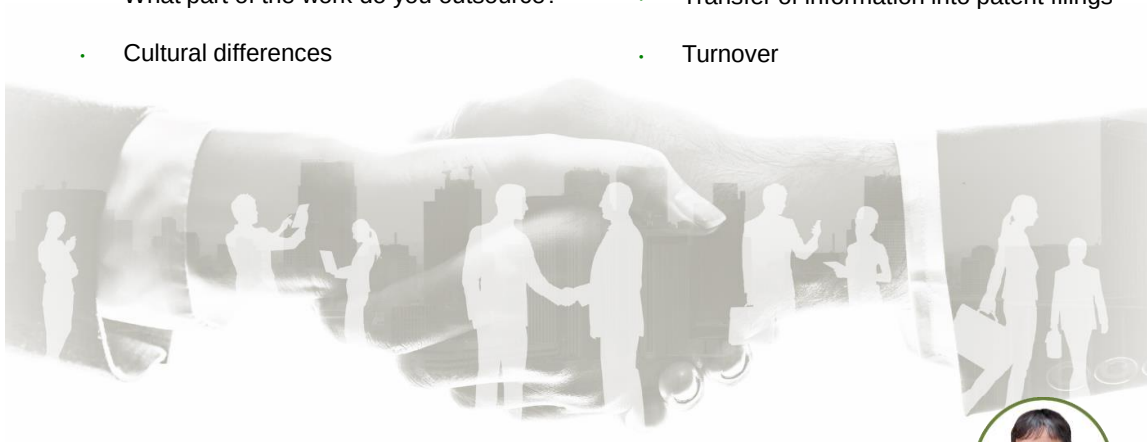
- FTE rates vs. what is my objective
- Compare apples to apples

Ask the right questions

36

IP Considerations

- What part of the work do you outsource?
- Cultural differences
- Transfer of information into patent filings
- Turnover



***Trust* is as important as a CDA**

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Data Sharing and Data Integrity

- What part of the work do you outsource?
- Access to raw data
- Turnover

Make sure the data are complete, consistent and accurate throughout the project and the data lifecycle

https://www.pharmaceutical-technology.com/compliance-consulting-and-training/data-integrity-pharma-nsf

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Academic vs. Industrial Collaborations

Academic

- At the forefront of science
- Lower cost
- Level of understanding of industry mindset
- Speed of execution
- Next steps?
- IP

Industrial

- Therapeutic area expertise
- Higher cost
- Next steps?
- IP

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Turnover and Problem Solving Skills

Turnover

- Stability of the workforce
- Access to legacy information
- Protection of intellectual property

Problem Solving Skills

- Level of training of workforce
- Understanding of areas of expertise
- Firewall model
- Open access to collective knowledge base

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Communication

- Written (ppt, written reports)
- Oral (TCs and project meetings)
- Cultural (east/west – north/south)
- Time zones
- Face-to-face meetings

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Audience Survey Question

ANSWER THE QUESTION ON BLUE SCREEN IN ONE MOMENT

In the next 3 to 5 years, my organization will…

- Increase its reliance on CROs
- Decrease its reliance on CROs
- Keep its reliance on CROs unchanged
- Question not applicable to me

** If your answer differs greatly from the choices above tell us in the chat!*

In Summary

- The past 20 years have seen a dramatic transformation of how pharma and biotech execute their science
- This trend is irreversible and CROs are here to stay
- Initial driver of outsourcing was cost

Today's drivers are multiple and include:

- Access to expertise and technologies
- Intellectual input
- High quality execution
- Risk sharing

Choosing the right partner can mean

the difference between success and failure!

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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019

Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework, careful planning of timing and projected costs to secure needed regulatory approvals is essential.

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What You Will Learn

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- The current regulatory framework is product specific, currently morphing and complicated by global trade issues
- To be most effective, intellectual property strategy needs to be tied to business goals, and focused on developing offensive and defensive positions beyond the traditional "is it patentable" lens

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Thinking Outside the Pillbox: Lead Generation and Optimization in Crop Protection Research

Drug Design and Delivery Series | September 19, 2019

Over the past 50 years, crop protection has evolved from using pesticides in high use rate to applying safer, selective, and more efficacious products, which share many of the features of modern drugs. Resistance development and environmental concerns are key drivers in the search for new, improved agrochemicals, which are currently discovered and optimized following a complex and demanding path similar to that followed in drug discovery.

Join Fides Benfatti of Syngenta Crop Protection during this free interactive broadcast as she demonstrates through various case studies much like Drug Discovery, crop protection research is a daunting challenge that has to be faced with world-class science where both industries can gain valuable insight from each other.

EXPERTS

Fides Benfatti
Syngenta Crop Protection

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What You Will Learn

- What are the challenges to identify safe, selective, and efficacious agrochemicals
- How these challenges are addressed, revealed through case studies
- Similarities and differences between crop protection and pharmaceutical research

https://www.acs.org/content/acs/en/acs-webinars/drug-discovery/compound-designs.html

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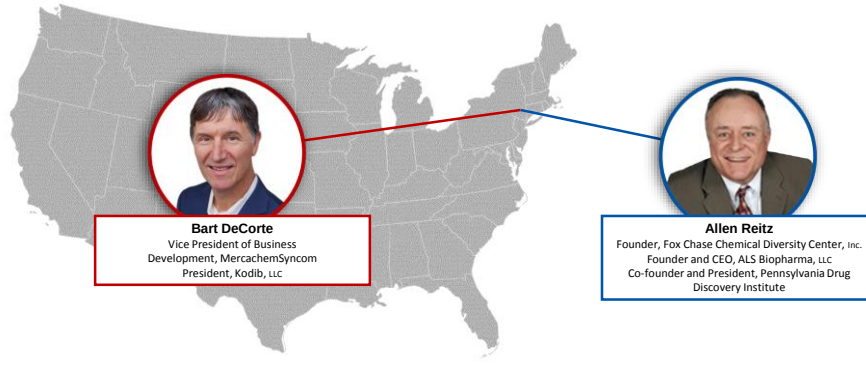
The Evolving Outsourcing Landscape in Pharma R&D: Pros and Cons of Different Models



Presentation slides available now! Recordings are an exclusive ACS member benefit.

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This ACS Webinar is co-produced with the ACS Division of Medicinal Chemistry, American Association of Pharmaceutical Scientists, and ACS Publications

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"I came to the webinar without any previous knowledge of the topic presented and was expecting the content to be largely over my head. Instead, I found the webinar to be both approachable and informative. I enjoyed this ACS Webinar presentation."

Fan of the Week

Kyla Hoggins
Student, Skagit Valley College

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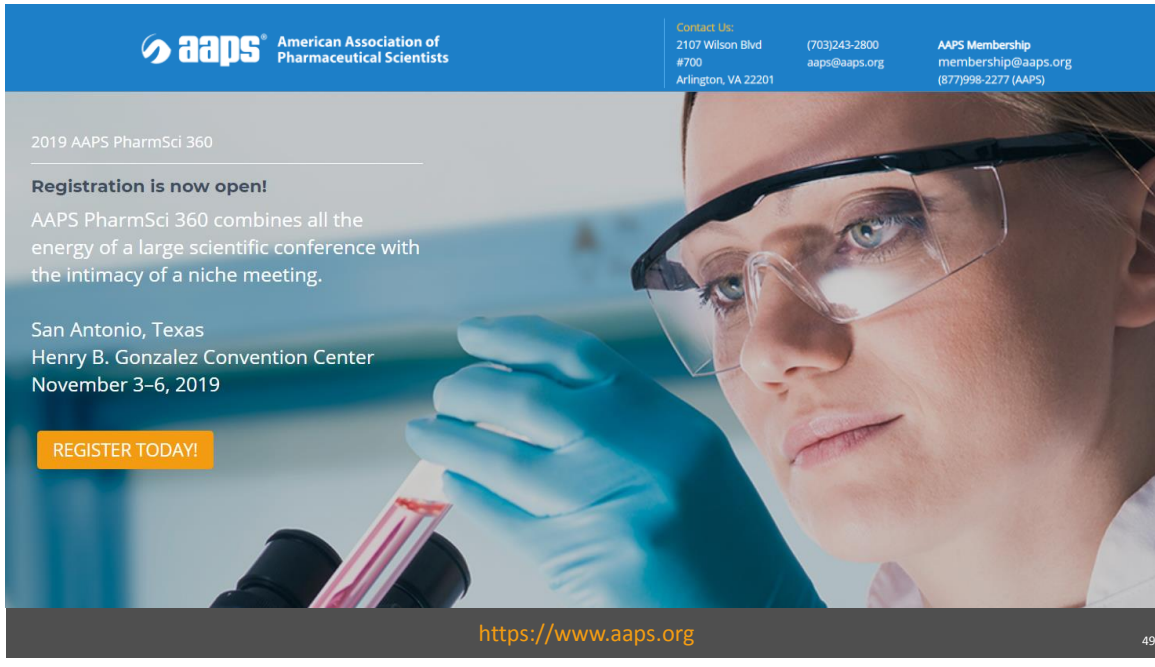

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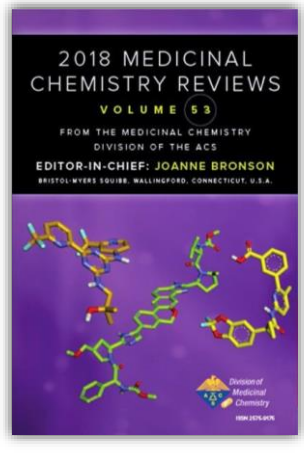

For $25 ($10 for students)**, You Will Receive:**

- A free digital copy of our annual medicinal chemistry review volume (over 680 pages, $160 retail price)
- Abstracts of MEDI programming at national meetings
- Access to student travel grants and fellowships

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IP & Regulatory Issues in Gene Editing

ACS Webinars | September 5, 2019

Researching genetics can be complicated, the regulations and IP issues surrounding them can be even more so.

Decisions requiring IP and regulatory guidance are deeply embedded from early discovery through post-launch phases of product development. IP strategy needs to be tied to business goals, directed to the specific R&D pipeline, and evergreen. Due to the fact that all organisms are not treated the same, and the asynchronous nature of the global regulatory framework, careful planning of timing and projected costs to secure needed regulatory approvals is essential.

What You Will Learn

- Working with gene editing technology poses unique intellectual property and regulatory challenges, from the R&D discovery through post-launch phases of the product development lifecycle
- The current regulatory framework is product specific, currently morphing and complicated by global trade issues
- To be most effective, intellectual property strategy needs to be tied to business goals, and focused on developing offensive and defensive positions beyond the traditional "is it patentable" lens

EXPERTS

Cassie Edgar
McKee, Voorhees & Sease

Jonathan Kennedy
McKee, Voorhees & Sease

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https://www.acs.org/content/acs/en/acs-webinars/business-entrepreneurship/gene-editing.html

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