FierceBiotech

Drug Development

Executive-level networking for better collaboration, more effective funding strategies and more productive R&D

September 25-27, 2017 // Renaissance Boston Waterfront Hotel // Boston, MA

2nd Forum

SPONSORS

Interact with fellow biotech leaders and trade ideas for tackling the biggest industry challenges, from preclinical research through pivotal trials and beyond!

FOUR PROGRAMMING TRACKS

† STRATEGIC DEAL-MAKING
• Reorient funding efforts in an uncertain IPO landscape
• Pioneer novel deal structures for today’s marketplace
• Identify M&A and licensing approaches that work

† IMPROVE R&D OUTCOMES
• Prioritize cost-effectiveness and value to ensure payoff for innovation
• Fine-tune partnerships and teams for clinical planning and trials
• Put patient engagement at the center of research

† CLINICAL RESEARCH OUTSOURCING & TECHNOLOGY
• Improve interactions with external partners through better planning and training
• Find the right partners and structure contracts more effectively
• Speed the transfer from preclinical research to clinical trials

† DIGITAL TECHNOLOGY AND REAL-WORLD EVIDENCE
• Put real-world evidence to work on new indications
• Tap novel medical devices and wearables for better clinical data
• Accelerate development with patient engagement and social media

Angus Grant
Vice President, Regulatory Affairs, Finance
CELGENE

Edward Kaye
CEO, SAREPTA THERAPEUTICS

Cynthia Schwalm
President, North American Commercial Operations, IPSEN

Chandra Ramanathan
Vice President and Head, East Coast Innovation Center
BAYER

Sara Nochur
Senior Vice President, Regulatory Affairs, ALNYLAM PHARMACEUTICALS

Rob Scott
CMO, ABBVIE

Roy Baynes
Senior Vice President, Head of Clinical Development, MERCK

Bryan Wornson
Vice President, Global Health and Value
PFIZER

Jeremy Chadwick
Vice President and Head, Global Clinical Development Operations, Shire

Gail Cawkwell
CMO, PURDUE PHARMACEUTICALS

Shakti Narayan
Vice President, Head of Transactions
JOHNSON & JOHNSON

3 Days
90+ Speakers
Unmatched Expertise And Influence

3 Tracks
350+ Attendees
10+ Hours of Networking

3 Days
4 Tracks
350+ Attendees
4 In-Depth Workshops
10+ Hours of Networking

Spokesperson
WHO SHOULD ATTEND
This event is aimed at professionals in the pharmaceutical, biotech, medical device and venture capitalist fields responsible for:
› Business Development
› Corporate Development
› Mergers & Acquisitions
› Alliance Management
› Partnering
› Portfolio Management
› Vendor Management
› Licensing
› Clinical Operations
› Clinical Research / Clinical Development
› Strategy / Product Strategy / Strategic Development
› Clinical Trial Management
› Data Management
› Innovation
› Investments
› R&D
› Regulatory Affairs

This event is also of interest to:
› CROs
› Supply chain professionals
› Law firms
› Clinical data management specialists
› Business development specialists

Dear Colleague,
The biotech industry faces many serious strategic challenges with no obvious solution. The FDA approved only 22 new drug candidates in 2016 – less than half of the prior year, and the lowest level since 2010. Meanwhile, the IPO market collapsed to its lowest level since 2009, and pressure from the government and payers is pushing pricing and value concerns into earlier stages of drug development.

Biopharma companies must increasingly adopt creative dealmaking, new digital technologies and early cost-effectiveness strategies, all while speeding up the R&D process. This requires a novel way of thinking about partnerships and pipeline strategies, from the highest levels of biopharma leadership.

The 2nd annual FierceBiotech Drug Development Forum will draw together the industry’s executive decision-makers, to help guide your companies to success throughout the entire life cycle – both for products and for companies themselves.

This year’s all-new agenda was built entirely from audience feedback, and offers you:

- Over 90 industry speakers, with >90% at the VP level or C-suite
- A three-day conference featuring four detailed learning tracks:
  › Strategic Deal-Making
  › Clinical Research Outsourcing and Technology
  › Improving R&D Outcomes
  › Digital Technology and Real-World Evidence
- Four long-format workshops offering deep dives into critical industry topics:
  › Accelerate Design of Adaptive Clinical Trials for Different Patient Populations
  › Encourage Growth of Partnerships Between Biotech and Academia
  › Make Meaningful Advances in a Hyper-Competitive Immuno-Oncology Market
  › Reduce the Failure Rate in CNS Trials by Managing Placebo Response
- Learning and networking opportunities with over 350 biotech industry leaders

This event gives biopharma leaders the skills to improve their partnership strategies with larger companies, financing sources and outsourced research partners. Our experienced and savvy executive-level speaking faculty will help you shape, select and pitch the best partnerships for drug development, while successfully navigating the financial and regulatory changes arising from a new administration. Target your learning opportunities toward four full-length tracks:

- STRATEGIC DEAL-MAKING: Develop novel deal structures, improve VC relationships, assess the M&A landscape and cope with a weak IPO market
- CLINICAL RESEARCH OUTSOURCING & TECHNOLOGY: Ensure success in highly partnered business models and move quickly from preclinical to clinical development, by streamlining relationships with your CROs
- IMPROVING R&D OUTCOMES: Step up R&D productivity through better patient engagement and recruiting, while demonstrating differentiation and value for demanding payers and physicians
- DIGITAL TECHNOLOGY & REAL-WORLD EVIDENCE: Use wearables, biomarkers and other technologies to accelerate clinical development and generate real-world evidence for the new health data ecosystem

On behalf of FierceBiotech and ExL Events, I invite you to join this unparalleled opportunity to work with your peers toward a quantum leap in drug development productivity and speed.

I look forward to seeing you in Boston this fall!

Sincerely,
Matt Greenbaum
Production Team Leader
ExL Events, a Division of Questex, LLC

Rebecca Williamson
Vice President, Life Sciences & Healthcare
FierceMarkets
Meet Your Drug Development Forum Speaking Faculty

Michael Aberman, Vice President, Strategy and Investor Relations, REGENERON
Estuardo Aguilar, CEO, ADVANTAGENE
Richard Anders, Founder, MASS MEDICAL ANGELS
Michael Bailey, CEO, AVEO ONCOLOGY
Roy Baynes, Senior Vice President, Head of Clinical Development, MERCK
Jeremy Bender, COO, TIZONA THERAPEUTICS
Lewis Bender, CEO, INTENSITY THERAPEUTICS
Donald Bergstrom, CMO, MERSANA THERAPEUTICS
Carl Berke, Partner, PARTNERS HEALTHCARE VENTURES
Kevin Bitterman, Partner, POLARIS PARTNERS
Steve Brannan, CMO, KARUNA PHARMACEUTICALS
Richard Brudnick, Executive Vice President, Business Development, BIOVERATIV
David Brush, Senior Director, Transactions, JOHNSON & JOHNSON
Christine Carberry, COO, KERYX BIOPHARMACEUTICALS
Gail Cawkwell, CMO, PURDUE PHARMACEUTICALS
Jesse Cedarbaum, Vice President, Clinical Development, BIOGEN
Jeremy Chadwick, Vice President and Head, Global Clinical Development Operations, SHIRE
Josh Cohen, CEO, AMYLX PHARMACEUTICALS
Ron Cohen, CEO, ACORDA THERAPEUTICS
Michael Cola, CEO, AEVI GENOMIC MEDICINE
Laurence Cooper, CEO, ZIOPHARM
Deborah Dunsiere, Principal, SOUTHERN CROSS BIO
Neal Farber, CEO, NEUROHEALING PHARMACEUTICALS
Maria Fardis, CEO, LION BIOTECHNOLOGIES
Maurizio Fava, Director, Division of Clinical Research, MGH RESEARCH INSTITUTE
Mitchell Finer, CEO, ONCORUS
Greg Fiore, CMO, SYNEDGEN
Dennis Ford, CEO, LIFE SCIENCE NATION
Karen Gardner, Senior Director, Clinical Development Operations, SEQRUS
Angus Grant, Vice President, Regulatory Affairs, Finance, CELGENE
Carolyn Green, Executive Director, Strategic Investments, Worldwide R&D, PFIZER
Luba Greenwood, Vice President, Global Mergers, Acquisitions and Business Development, ROCHE
Richard Gregory, CSO, IMMUNOGEN
Jessica Grossman, CEO, MEDICINES360
Mike Hale, Vice President and Head of Biostatistics and Programming, SHIRE
Scott Harris, CMO, LYRIC PHARMACEUTICALS
Dana Hilt, CMO, LYSOSOMAL THERAPEUTICS
John Hohneker, Executive Vice President, Head of R&D, FORMA THERAPEUTICS
Martin Huber, CMO, TESARO
Stephen Isaacs, CEO, ADURO BIOTECH
Eva Jack, CBO, MERSANA THERAPEUTICS
Kenneth Kaitin, Director, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Edward Kaye, CEO, SAREPTA THERAPEUTICS
Justin Klee, President, AMYLX PHARMACEUTICALS
Isaac Kohane, Chair, Department of Biomedical Informatics, HARVARD MEDICAL SCHOOL
William Korinek, CEO, ASTROCYTE PHARMACEUTICALS
Pablo Lapuerta, Executive Vice President and CMO, LEXICON PHARMACEUTICALS
John Lee, CMO, PHASEBIO PHARMACEUTICALS
Liz Lewis, Chief Counsel, Head of Patient Advocacy, TAKEDA
Casey Logan, CBO, TRACON PHARMACEUTICALS
Timothy Lowinger, CSO, MERSANA THERAPEUTICS
David Loynd, CEO, ENDURX PHARMACEUTICALS
Krishna Menon, CSO and President of Research, CELLCEUTIX
Michael Metzger, President and COO, SYNDAX
Ramon Mohanal, CMO, BEYONDSPRING PHARMACEUTICALS
Jodie Morrison, CEO, TOKAI PHARMACEUTICALS
Rich Murray, CEO, JOUNCE THERAPEUTICS
Shakti Narayan, Vice President, Head of Transactions, JOHNSON & JOHNSON
Melissa Nelson, Senior Global Project Manager, MEDTRONIC
Sara Nochur, Senior Vice President, Regulatory Affairs, ALNYLAM PHARMACEUTICALS
Denis Patrick, Executive Director, Head, External R&D Innovation, PFIZER
Matt Portch, Vice President, Managed Markets, SUNOVION
Amit Rakhit, CMO, OVID THERAPEUTICS
Chandra Ramanathan, Vice President and Head, East Coast Innovation Center, BAYER
Rosemary Reilly, Partner, WILMER HALE
Katie Reilly-Gauvin, Vice President, Global Commercial Development, ABBVIE
Jane Rhodes, Senior Director, New Innovations, BIOGEN
Lindsay Rosenwald, CEO, FORTRESS BIOTECH
Natalie Sacks, CMO, ADURO BIOTECH
Tehseen Salimi, Vice President, Medical Affairs, TREVENA
Cynthia Schwalm, President, North American Commercial Operations, IPSEN
Rob Scott, CMO, ABBVIE
David Sherris, CEO, GENADAM THERAPEUTICS, Neal Simon, CEO, AZEVAN PHARMACEUTICALS
David Soergel, CMO, TREVENA
Andrew Storey, Vice President, Global Regulatory Strategy, ABBVIE
P.K. Tandon, Senior Vice President, Biometrics & Development Strategy, ULTRAGENYX
Steve Targum, CMO, FUNCTIONAL NEUROMODULATION
Charles Theuer, CEO, TRACON PHARMACEUTICALS
Doug Treco, CEO, RA PHARMACEUTICALS
Nancy Valente, Vice President, Global Product Development, GENENTECH
Maria Vilenchik, CEO, FELICITEX THERAPEUTICS
Sue Washer, CEO, APPLIED GENETIC TECHNOLOGIES CORPORATION
Jeff Wiezorek, Senior Vice President, Clinical Development, KITE PHARMA
Keith Wilcoxen, Senior Director, Scientific R&D, TESARO
Leslie Williams, CEO, IMMUSANT
Bryon Wornson, Vice President, Global Health and Value, PFIZER
Andrew Young, CSO, INTARCIA THERAPEUTICS
Steven Zelenkovskie, Vice President, Cardiovascular Medical Affairs, Therapeutic Area Head, ASTRAZENECA
9:00 Accelerate Design of Adaptive Clinical Trials for Different Patient Populations

Recent success in biomarker development has made patient stratification in clinical trials a reality. But now with so many trial design options available, it can be a challenge to select the one best for your pipeline.

- Generate usable data quickly and with as few trials as possible
- Navigate pathways through FDA for breakthrough designation
- Learn from successful early design case studies

Steven Zelenkofske, Vice President, Cardiovascular Medical Affairs, Therapeutic Area Head, ASTRAZENECA
Martin Huber, CMO, TESARO
P.K. Tandon, Senior Vice President, Biometrics & Development Strategy, ULTRAGENYX
Scott Harris, CMO, LYRIC PHARMACEUTICALS

Encourage Growth of Partnerships Between Biotech and Academia

Academic researchers often have more leeway for early research than industry will. By properly cultivating this, biotech companies can improve the likelihood of gaining access to successful new molecules.

- Leverage braintrusts which are very deep in university environments by sharing authorship and manuscripts
- Gain exposure to the granting and review functions
- Synergistically turn research into real medicine

Stephen Isaacs, CEO, A DURO BIOTECH
Michael Metzger, President and COO, SYNDAX

*This session contains a 30 minute networking break

12:00 Luncheon

1:00 Make Meaningful Advances in a Hyper-Competitive Immuno-oncology Market

Immunotherapies represent the next “blockbuster” sector, but with hundreds of candidates already being explored, some companies may take on inappropriate risk when trying to differentiate their candidates. Hone in on better ways to structure multi-armed trials, attract patients and secure regulatory approval.

- Avoid irrationality in trial design resulting from attempts to be first to market
- Beware of regulators growing tired of “wasting patients” on the latest PD1 investigation
- Mix, match and add to multiple conventional therapies at once

Natalie Sacks, CMO, A DURO BIOTECH
Mitchell Finer, CEO, ONCORUS

Reduce the Failure Rate in CNS Trials by Managing Placebo Response

Drugs for neurological disorders are notoriously challenging in the clinic for many reasons, among them endpoint selection and the physiological obstacles faced by some patient populations and ages. Placebo response has been a major cause of trial failure, and new in-depth research has the potential to significantly mitigate this.

- Outline why CNS trials are particularly prone to failure
- Examine the challenges faced in trials for depression, schizophrenia and other indications
- Select patients disproportionately likely to respond to placebo

Dana Hilt, CMO, LYSOSOMAL THERAPEUTICS
Steve Brannan, CMO, KARUNA PHARMACEUTICALS
Steve Targum, CMO, FUNCTIONAL NEUROMODULATION
Maurizio Fava, Director, Division of Clinical Research, MGH RESEARCH INSTITUTE

*This session contains a 30 minute networking break
8:00  Registration and Continental Breakfast

8:45  Opening Remarks

Rebecca Willumson, Vice President, Life Sciences & Healthcare, FIERCEMARKETS, A DIVISION OF QUESTEX LLC

9:00  Chart the Clearest Path to Drug Approval

• Spot trends in the new FDA commissioner’s previous commentary on the approvals process
• Outline new FDA initiatives to accelerate drug approval, with applications for orphan drugs, breakthrough designation and real world evidence
• Focus on challenges in NDAs, including new types of data, earlier-stage trials and small studies

Maria Fardis, CEO, LION BIOTECHNOLOGIES

9:50  Networking Break

10:00  Industry Strategy on Drug Pricing: Making a Better Second Impression

• Prepare biopharma companies to face tremendous pricing pressure from payers, scrutiny from politicians and controversy in the public sphere
• Explore the ways pricing pressure effects innovation and R&D go/no-go decisions
• Assess whether biopharma can count on the U.S. market to fund global R&D going forward and discuss possible alternatives

Moderator:
Carly Helfand, Senior Editor, FIERCEMARKETS

Panelists:
Ron Cohen, CEO, ACORDA THERAPEUTICS
Edward Kaye, CEO, SAREPTA THERAPEUTICS
Kenneth Kaitin, Director, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT
Bryon Wornson, Vice President, Global Health and Value, PFIZER

10:50  Networking Break

11:00  Cultivate Diversity in the Biotech Sector

• Set up metrics when working with recruiting firms so you don’t stifle your own initiatives
• Track the growth and acceptance of industry best practices since controversies of 2015
• Discuss the power differentials among women on executive or board of director level in both biotech and pharma

Moderator:
Tracy Staton, Editor in Chief, FIERCEBIOTECH

Panelists:
Jessica Grossman, CEO, MEDICINES360
Katie Reilly-Gauvin, Vice President, Global Commercial Development, ABBVIE
Nancy Valente, Vice President, Global Product Development, GENENTECH

11:50  Networking Break

12:00  Fierce15 Veterans Panel: Lessons Learned on the Journey

• Learn from past Fierce15 winners who’ve transitioned from private to public
• Hear the how-tos of partnerships with larger drugmakers, manufacturers and more
• Share insights on working with investors and developing management teams

This session will feature dynamic speakers from previous Fierce15 winning organizations.

12:30  Luncheon

Tuesday, September 26, 2017 // MAIN CONFERENCE, DAY ONE

Strategic Deal Making

1:45  Presentation by Deloitte

Prepare a Full Clinical Development Plan with External Partners in Mind

• Extend your costing and budgeting beyond phase-II and determine how contractors fit into these estimates
• Firm up your internal and external development strategies
• Identify and evaluate potential partners

Jeremy Chadwick, Vice President and Head, Global Clinical Development Operations, SHIRE

Ensure that Innovative R&D Companies are Rewarded for Taking Risks

• Ensure that targets you prosecute will actually be difference-makers
• Evaluate the unmet medical need, its current economic and productivity burden and the economic benefit of the drug candidate in light of those figures
• Navigate potential failure points from a regulatory, cost and reimbursement point of view

David Soergel, CMO, TREVENA
Doug Treco, CEO, RA PHARMACEUTICALS
Rob Scott, CMO, ABBVIE

Meet Increasing Demands for Real-World Evidence

• Differentiate between pivotal phase-III trials and real-world evidence
• Prepare evidence of outcomes for regulatory, healthcare, insurers and other stakeholders
• Use alternate measuring and modeling techniques in early development programs

Donald Bergstrom, CMO, MERSANA THERAPEUTICS
### Strategic Deal Making

**2:30 Anticipate the Responses and Judgments of Venture Capitalists to a Crowded Market**
- Recognize the different levels of strategic investments deployed by VCs and their incentives for growing more conservative during an IPO downturn
- Understand their preferred signals for company viability and risk levels
- Justify the changes in value proposition that take place if a company has not been de-risked

**Moderator:** Rosemary Reilly, Partner, WILMER HALE  
**Panelists:** Luba Greenwood, Vice President, Global Mergers, Acquisitions and Business Development, ROCHE  
Eva Jack, CBQ, MERSANA THERAPEUTICS

### Clinical Research Outsourcing and Technology

**3:15 Enable Flexibility, Creativity and Independence in Partnerships Between Large and Small Biotech Companies**
- Recognize the importance of larger partners allowing programs to develop to late stage, guided by dialogue, but with smaller partners ultimately making the calls
- Allow smaller companies to control their own fate – keeping them excited and engaged in what they will do – by not leaving commercial rights exclusively with the larger company
- Insulate projects from deprioritization during portfolio review

**Michael Bailey, CEO, AVEO ONCOLOGY**  
Chandra Ramanathan, Vice President and Head, East Coast Innovation Center, BAYER  
Cynthia Schwalm, President, North American Commercial Operations, IPSEN  
Rich Murray, CEO, JOUNCE THERAPEUTICS

**Prioritize Late-Stage Development Programs**
- Reorient development around drugs that have reached pivotal trials for at least one indication
- Gauge interest among investors and the medical community
- Clarify the status of drugs in pivotal trials in your portfolio and among M&A prospects

**Gail Cawkwell, CMO, PURDUE PHARMACEUTICALS**

**Ensure Success in a Highly-Partnered Business Model**
- Recognize the need to build competence in a partnered model across the entire company
- Allocate enough resources, including capital, to make the alliance strategy work
- Execute against deals made and create the value needed to justify that investment

**Greg Fiore, CMO, SYNDENGE**  
Tehseen Salimi, Vice President, Medical Affairs, TREVENA

### Improving R&D Outcomes

**Transition to a More Personalized Approach to Working with Patients in Specialty Markets**
- Recognize that disease areas traditionally pursued by large pharma companies have grown smaller and more personalized
- Discuss the changes in specialty markets, regulatory approval pathways and primary care requirements
- Reduce risks of large prolonged clinical programs through improved targeting of specific disease and population types
- Determine whether your development program can qualify for the FDA’s Breakthrough Pathway

**Roy Baynes, Senior Vice President, Head of Clinical Development, MERCK**

**Accelerate Product Concept to Clinical Testing by Going Well Beyond the Virtual Company Model**
- Rapidly advance drugs without academic / institutional discovery, VC funding or proprietary lab space
- Learn the five key insights one must have to be successful at getting to the clinic quickly
- Master the core development fundamentals of nonclinical testing, regulatory interaction, CMC and clinical protocol design

**Lewis Bender, CEO, INTENSITY THERAPEUTICS**

### Digital Technology and Real-World Evidence

**Would you like to sponsor this session?**
- Spread the word about your organization’s expertise and leadership
- Highlight your successes in clinical research partnerships
- Help biotech companies overcome a period of financial and legislative uncertainty

**To add your expert voice to the program, contact Andrew Sinetar at asinetar@exlevents.com or 212-400-6237**

**Bring Novel Medical Devices and Wearables to Bear on Clinical Trials**
- Grasp how new technology can be introduced in your clinical trial
- Outline emerging applications of wearables and mobile devices in clinical trials
- Examine the impact of positive patient experience on compliance and sample size
- Use digital information and apps to generate payer-friendly data

**Melissa Nelson, Senior Global Product Manager, MEDTRONIC**  
Jesse Cedarbaum, Vice President, Clinical Development, BIOGEN

### Networking Break
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Panelists</th>
</tr>
</thead>
<tbody>
<tr>
<td>4:30</td>
<td>Avoid Desperation by Precision Expectations with Venture Capitalists</td>
<td>Carolyn Green, Executive Director, Strategic Investments, Worldwide R&amp;D, PFIZER&lt;br&gt;Neal Simon, CEO, AZEVAN PHARMACEUTICALS</td>
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<tr>
<td></td>
<td>Focus on Sponsor Accountability for CRO Oversight</td>
<td>Jodie Morrison, CEO, TOKAI IMMUSANT</td>
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<tr>
<td>5:15</td>
<td>Evaluate the Risks and Benefits of Deal Complexity: What Really Generates Value?</td>
<td>Angus Grant, Vice President, Regulatory Affairs, Finance, CELGENE&lt;br&gt;Jeremy Bender, COO, TIZONA THERAPEUTICS</td>
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<td></td>
<td>Evaluate the Prospective Match Between CROs and Sponsors</td>
<td>Karen Gardner, Senior Director, Clinical Development Operations, SEQIRUS</td>
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<td></td>
<td>Add Orphan Indications to Accelerate Development</td>
<td>Krishna Menon, CSO and President of Research, CELLCEUTIX&lt;br&gt;John Lee, CMO, PHASEBIO PHARMACEUTICALS</td>
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<td>6:00</td>
<td>Cocktail Reception &amp; Fierce15 Awards</td>
<td>Isaac Kohane, Chair, Department of Biomedical Informatics, HARVARD MEDICAL SCHOOL</td>
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<td>7:00</td>
<td>Day One Concludes</td>
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</table>
### Strategic Deal Making

**Secure Funding for Preclinical Companies**
- Position company appropriately for financing
- Navigate a financing strategy
- Visualize advantages and disadvantages of investor-type financing

**How to Succeed in Novel Deal Structures (Even If They’re Trying)**
- Dialogue about options for licensing out preclinical assets, then bringing them back after development
- Look beyond popular formats and processes to determine execution strategy
- Learn as much from what other companies choose not to do

### Clinical Research Outsourcing and Technology

**Shorten the Path from Preclinical to Clinical Phases**
- Learn from large pharma and their expertise in advancing into the clinic
- Clarify strategies for bridging discovery and development
- Identify methods for advancing pipeline projects within targeted time frames

**Bridge the Cultural Divide Between Small Biotechs and Large CROs**
- Recognize that CROs are incentivized to gain efficiency at scale by dividing staff sharply along functional roles — which strongly differs from biotech start-up culture
- Align value with cost, given that there is no objective database for costs and that biotechs and CROs have very different incentives
- Agree on the depth and frequency of data verification and recognize when it is more appropriate to react to changes, amend protocols or start a new one

### Improving R&D Outcomes

**Fine-Tune Partnerships for Rare Disease Clinical Trials**
- Identify partners with the heft, infrastructure and commercialization experience that small biotechs typically lack
- Customize partnerships based on matching expertise and interest area
- Recognize that you cannot over-prepare for screening and enrolling sufficient patients to move through clinical development

**Build Internal Multi-Division Teams for Successful Product Advancement**
- Understand the intersections of R&D, regulatory, clinical and program management during product development
- Establish day-to-day project teams, where members from each functional area are equipped and supported to talk with colleagues
- Stimulate cross-functional interactions so the handoff goes well

### Digital Technology and Real-World Evidence

**Capitalize on Upcoming FDA Initiatives to Tap New Sources of Trial Data**
- Leap past shortcomings of registries and claims data to usable evidence
- Establish partnerships with tech players to prepare for bringing real-world data into the regulatory sphere
- Anticipate the concerns of regulators on data packages that incorporate alternative sources

**Bring Biomarkers, Patient Empowerment and Trial Design Together to Improve Drug Development Efficiency**
- Enable patient segmentation by making data available for open use
- Strike relationships between healthcare institutions and drug developers to identify patients who fit a target population
- Use new technologies to facilitate collecting standardized trial data

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| 8:00 | Continental Breakfast |
| 9:15 | Secure Funding for Preclinical Companies |
|      | How to Succeed in Novel Deal Structures (Even If They’re Trying) |
| 10:00 | Shorten the Path from Preclinical to Clinical Phases |
|      | Bridge the Cultural Divide Between Small Biotechs and Large CROs |
| 10:45 | Networking Break |
### Strategic Deal Making

**11:15 Highlight the Warning Signs of Failure in Strategic Partnerships**
- Eliminate gaps between signing deals and actually getting them into execution mode
- Avoid tensions in collaboration during or even before launch
- Figure out how to work together in order to maintain expected value

_Christine Carberry, COO, KERYX BIOPHARMACEUTICALS_

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**12:00 Build the Deal – Don’t Buy It**
- Explore the middle ground between licensing/M&A and venture investment
- Compare and contrast the differing objectives of strategic and venture investments
- Foster organic growth at targeted smaller companies to build them into more appealing buyout prospects

_David Brush, Senior Director, Transactions, JOHNSON & JOHNSON_

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### Clinical Research Outsourcing and Technology

**Conduct Research in an Externalized Environment**
- Select and manage CROs, biotech partners, academic investigators and internal resources to drive research
- Balance external and internal research efforts to drive integrated portfolio development
- Stay flexible to custom fit well aligned research to partners strengths

_Laurence Cooper, CEO, ZIOPHARM_

_Jeff Wiezorek, Senior Vice President, Clinical Development, KITE PHARMA_

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**Lower Clinical Development Time and Costs when Working in China**
- Identify the key drivers of the clinical trial process in China
- Highlight important differences in the patient enrollment process
- Accelerate regulatory review and approval

_Lan Huang, CEO, BEYONDSPRING PHARMACEUTICALS_

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### Improving R&D Outcomes

**Strategize First-In-Human CAR-T and TCR-T Study Designs**
- Engineer T cells to provide the same discrimination between friend and foe as endogenous T cells
- Identify the indications most fitting for CARs and/or TCRs
- Mitigate the costs of genetically modifying T cells

_Laurence Cooper, CEO, ZIOPHARM_

_Jeff Wiezorek, Senior Vice President, Clinical Development, KITE PHARMA_

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**Grasp Combination and Patient Engagement Approaches in Immuno-Oncology**
- Adapt to the development and use of models and preclinical pharmacology tools, which are in their infancy for translation to humans
- Confront differences between animal and human immunology, particularly the inherent plasticity and temporal dynamics of the immune system
- Clarify patient selection strategy through large multi-arm studies

_Estuardo Aguilar, CEO, ADVANTAGENE_

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### Digital Technology and Real-World Evidence

**Utilize Real-World Evidence to Bring Forward New Indications**
- Determine best methods for gathering follow-up data from patients being treated at market
- Focus on new uses and side effects
- Set your plans for real-world evidence gathering within FDA’s stated openness for its use

_Ramon Mohanlal, CMO, BEYONDSPRING PHARMACEUTICALS_

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**Attract Informatics Talent and Resources Necessary for Patient Centricity and Personalized Medicine**
- Identify your specific informatics needs and the technology expertise necessary
- Learn how to recruit informatics staffers with life sciences experience, partly by identifying PhD programs that emphasize computational skills
- Move beyond the company IT department to find tech-savvy scientific talent

_Michael Cola, CEO, AEVI GENOMIC MEDICINE_

_Mike Hale, Vice President and Head of Biostatistics and Programming, SHIRE_

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12:45 Networking Luncheon
## SPONSORSHIP & EXHIBIT OPPORTUNITIES

Do you want to spread the word about your organization’s solutions and services to potential clients who will be attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

### Strategic Deal Making

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Details</th>
</tr>
</thead>
</table>
| 1:45 | Pioneer Novel Deal Structures in a Changing Marketplace | - Strategically externalize assets with a deal structure that enables you to re-acquire it after they have reached proof of concept or other key milestones  
- Leverage partner expertise while sharing both risks and costs  
- Align financials and build trust to allow staged externalization to succeed  
Shakti Narayan, Vice President, Head of Transactions, JOHNSON & JOHNSON  
Casey Logan, CBO, TRACON PHARMA  
Charles Theuer, CEO, TRACON PHARMA |

### Clinical Research Outsourcing and Technology

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| 2:30 | Unlock the Value of Indications that are of Incubatory Interest to Larger Pharma | - Develop licensing interest in indications outside of pharma’s traditional “core” disease areas  
- Manage the stop and go conversations through trial design, investment, clinical results, valuation inflection points and deal execution  
- Compensate for asymmetrical information exchange between small and large companies  
David Loynd, CEO, ENDURX PHARMA  
William Korinek, CEO, ASTROCYTE PHARMACEUTICALS |

### Improving R&D Outcomes

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| 3:15 | Review Key Lessons and Future Applications for Gene Editing | - Spotlight major developments in CRISPR techniques  
- Weigh likely growth of partnerships for gene editing  
- Examine the impact on immuno-oncology  
Do you want to speak at this session? Please contact Andrew Sinetar at 212-400-6237 or asinetar@exlevents.com  
Matt Portch, Vice President, Managed Markets, SUNOVION  
Andrew Storey, Vice President, Global Regulatory Strategy, ABBVIE |

### Digital Technology and Real-World Evidence

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| 1:45 | Achieve Commercial Success with Peptide Therapeutics for Chronic Diseases through Target Selection and Product Planning | - Balance the attractiveness of having a platform with great potential applications against the reality of having to pick the application most likely to secure FDA approval  
- Pinpoint the ideal indication and label claims to seek  
- Model the best means for acquiring resources and presenting your R&D packages to larger pharma  
Andrew Young, CSO, INTARCIA THERAPEUTICS |

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<th>Time</th>
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<tr>
<td>3:15</td>
<td>Conference Concludes</td>
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</table>
VENUE
Renaissance Boston Waterfront Hotel
606 Congress Street
Boston, MA 02210

If you require overnight accommodations, please contact the hotel. ExL has reserved a block of rooms at a discounted rate for ExL participants. To make reservations, please call 1-800-228-9290 or 617-338-4111 and request the negotiated rate for DDF 2017. The group rate is available until September 5. Please book your room early, as rooms available at this rate are limited.

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Registration Fees for attending the 2nd FierceBiotech Drug Development Forum:

<table>
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<th>Category</th>
<th>Advanced Rate</th>
<th>Early Bird</th>
<th>Standard Rate</th>
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<tbody>
<tr>
<td>Pharma/Biotech – Conference Only</td>
<td>$1,595</td>
<td>$2,495</td>
<td>$795</td>
</tr>
<tr>
<td>Service Provider – Conference Only</td>
<td>$2,495</td>
<td>$2,695</td>
<td>$995</td>
</tr>
<tr>
<td>Academic – Conference Only</td>
<td>$795</td>
<td>$995</td>
<td>$1,195</td>
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Pre-Conference Workshops - Add on Pass: Choose from 1 AM and one PM Workshop — $300 each

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**Save 25% per person when registering four**

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register 4 at one time). This is a savings of 25% per person.

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Can only send three? You can still save 15% off of every registration. To find out more on how you can take advantage of these group discounts, please call 201 871 0474.

Questions/Comments

Do you have a question or comment that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader?

Method of Payment: ☐ Check ☐ Credit Card

Make checks payable to ExL Events.
Card Type:  ☐ MasterCard ☐ Visa ☐ Discover ☐ AMEX

Card Number: ____________________________ Exp. Date: _______________ CVV: ___________
Name on Card: ____________________________
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CONFERENCE CODE: C942
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• Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

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Scenes from the Drug Development Forum 2016