3rd Human Abuse Liability & Abuse-Deterrent Formulations

Adapting to New Regulations and Improving Market Success by Demonstrating Reduction of the Abuse Potential in Prescription Drugs

November 2-3, 2016 | Hilton Crystal City at Reagan National Airport | Arlington, VA

The leading industry event on reducing the abuse potential of prescription opioids — and the FIRST conference held after release and comment on FDA’s draft guidelines for abuse-deterrent generic drugs!

Adapt to the Latest Regulatory and Reimbursement Obstacles

- INDIVIOR Redesigns Outreach to Payers and Physicians
- JOHNSON & JOHNSON Highlights Political Outcomes Most Likely to Impact ADF Uptake
- COLLEGIUM PHARMA Explores Likely Changes in Payer Priorities
- GRUNENTHAL Spotlights Key Learning Opportunities from the FDA Advisory Committee Process
- EGALET Adapts to Extra Scrutiny for Improved Label Claims

New Strategies to Improve and Document Abuse Deterrence

- ENSYSCE Reviews the Current and Future Prospects for Prodrugs
- KEMPHARM Assesses Endpoint Selection in Abuse Liability Studies
- ADC Forecasts the Development Life Cycles and ROI of Multiple ADF Technologies
- BRAEBURN PHARMA Reorients ADFs Toward Non-Analgesic Opioids
- SAREPTA THERAPEUTICS Harmonizes Multiple Drug Surveillance Databases

“Great presentations and very comprehensive review of clinical trial requirements.”
—Principal Scientist, Safety Pharmacology and Drug Safety, PFIZER

“Shared great, informative approaches for overcoming challenges associated with opioid abuse.”
—Director, Formulations, RECKITT BENCKISER
Dear Colleague,

This spring, the FDA released the long-awaited draft guidelines that brought generic drug manufacturers into the abuse-deterrent formulations market. This new regulatory framework comes at a time when public concerns about abuse of prescription opioids has never been higher — and yet the obstacles to market uptake remain due to payer and prescriber hesitancy. This period of upheaval is why you cannot afford to miss the 3rd Human Abuse Liability & Abuse-Deterrent Formulations conference — the largest and most specifically focused educational event devoted to improving trial designs, engineering less abuse-prone molecules and delivery systems, and tracking the performance and market uptake of opioids in order to document the success of abuse-deterrent methods. Over the past three years this event has brought more than 200 industry leaders together, and this year is going to have our most in-depth educational and networking opportunities yet!

Our expert speaking faculty will help you:

- Adapt to the latest regulatory guidelines for branded and generic opioids
- Target the most important lessons from FDA advisory committee meetings
- Minimize abuse risk through prodrug technologies, agonist/antagonist formulations and novel delivery mechanisms
- Find the data necessary to document the uptake and abuse rate of specific opioid types
- Make the case to physicians, payers and patients that your opioids truly are less of an abuse risk

WHO SHOULD ATTEND:
This conference is designed for pharmaceutical, biotech, specialty, generic, and medical device professionals responsible for:

- Regulatory Affairs/Intelligence
- Epidemiology/Pharmacoepidemiology
- Clinical Development/Operations/Affairs/Programs
- Risk Management/REMS
- Toxicology
- Drug Safety
- Pharmacology/Clinical Pharmacology/Safety Pharmacology
- CNS/Neuroscience
- Medical Affairs
- Scientific Affairs
- Formulations
- Analytical Development
- R&D
- Pharmacovigilance
- Pharmacoeconomics/Health Economics/Outcomes Research/HEOR
- Commercial Affairs
- Legal Affairs/Legal Counsel
- Government Affairs
- Business Affairs
- Medical/Promotional Review

This event is also of interest to:

- CROs
- Toxicology Specialists
- Drug Abuse Registry/Surveillance Specialists
- REMS/Pharmacovigilance Specialists
- Formulation Service Providers
- Pharmacokinetics Service Providers
- Abuse Liability Service Providers
- Regulatory Specialists
- Intellectual Property Service Providers

VENUE
Hilton Crystal City at Reagan National Airport
2399 Jefferson Davis Hwy
Arlington, VA 22202

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 1-800-695-7551 and request the group rate for ExLs November Meetings. The group rate is available until October 6, 2016. Please book your room early, as rooms available at this rate are limited.

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Chairperson’s Opening Remarks

9:00 Prepare for Political Outcomes Most Likely to Impact ADF Uptake

Spring 2016 saw the creation of more than a dozen congressional bills encouraging ADF development as part of the broader CARA initiative. Coupled with new initiatives from state legislatures, this trend suggests that lawmakers will be less of an obstacle for ADF adoption than payers.
- Use epidemiology data to link payer considerations for ADF reimbursement to their drug addiction treatment coverage
- Highlight where even apparent defeats for ADF developers come from a position of political weakness and unpopularity
- Move from philosophical to practical approaches

Jeff Buel, Director, State Government Affairs, JOHNSON & JOHNSON

Forecast the Legislative Changes That Can Impact Reimbursement Prospects for ADFs

Private health insurers and the CMS have proven to be very skeptical of the need for ADFs. No amount of drug development will be worthwhile if the product stays on shelves, so bipartisan Congressional groups and patient advocate organizations are working to shift perceptions among the payer community.
- Recognize the weaknesses of insurer “Fail-First” policies
- Anticipate the wider need for educational outreach as states pass their own laws
- Compare and contrast the approaches of Medicare and Medicaid based on the prescription drug abuse routes of senior citizens

Tim Hermes, Vice President, Government Affairs and Alliance Development, COLLEGIUM PHARMACEUTICALS

Confront Regulatory Contradictions that Negatively Impact Drug Surveillance

New guidelines in 2016 require generic drugs to look similar to reference drugs in order to improve patient adherence. But how much similarity is required? If both versions look identical, it is impossible to carry out category-IV surveillance, even though the FDA also requires this for drugs with abuse potential.
- Clarify the importance of drug distinguishability when measuring ADFs against steady criteria
- Predict the impact of new generic guidelines on the rigor of postmarketing studies
- Deliver comments and work with the FDA for clarification

Simon Budman, CEO, INFLEXXION

10:30

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11:15 Networking Break

11:45 Identify Essential Elements of Federal and State Legislation to Foster Transition to ADFs

New legislation addressing ADFs will go before lawmakers in early 2017. Consensus recommendations from informed stakeholders should form the basis of legislative proposals to spur and speed ADF development, and ensure parity of coverage.

Wendy Niebler, Senior Vice President, Clinical Development and Medical Affairs, EGALET
3:45 Networking Break

4:15 Gain the Patient’s Perspective on ADF Testing and Uptake
The needs of the chronic pain patient must be at the forefront of your abuse liability trial design, as well as your market outreach to improve the future of your drugs. Their interactions with prescribing physicians and insurance companies can also provide valuable insight for your own campaigns.
- Review the patient experience in trials for ADFs
- Follow patient priorities and conversations about using new ADFs
- Internalize patient concerns about the risks of prescription opioid abuse

Paul Gileno, CEO, U.S. PAIN FOUNDATION

5:00 Achieve a Culture of Cooperation Between Payers and Physicians While Understanding the Opioid Patient Journey
Educating physicians and working with payers helps cultivate an atmosphere of understanding the chronic nature of opioid use disorder. Varying coverage levels in opioid use disorder medications among states can pose possible challenges in accessing treatment for many patients — how much of this can you foresee and avoid?
- Take a state-by-state assessment of differing coverage levels for opioid dependence treatment access to specific patient populations

5:45 Networking Reception

6:45 Day One Concludes

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Thursday, November 3, 2016

8:00 Continental Breakfast

8:45 Introduction from Track Chairperson

9:00 Reexamine Clinical Endpoints in Human Abuse Potential Studies
The FDA increasingly relies on Drug Liking as the primary endpoint in human abuse potential studies. But there are a host of other potential endpoints that should be considered to gain a comprehensive understanding of the rewarding effects, and, in turn, the abuse potential of a drug or drug formulation. Some endpoints used for extended release opioids may not be suitable for immediate release opioids.
- Understand the historical perspective on Drug Liking as the primary endpoint
- Compare and contrast the appropriateness of multiple potential endpoints
- Reconsider abuse potential study designs and endpoints that were not developed to discriminate potential differences between formulations
- Delve into literature to refine endpoint specificity
- Consider alternative endpoints in the context of current FDA guidance

Andrew Barrett, Senior Director, Scientific Affairs, KEMPHARM

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Spotlight the Abuse Risks and Technical Options for IR Opioids
The lack of abuse-deterrent formulations among immediate release opioids has had a significant impact on trends in opioid abuse. New technological developments can help minimize the abuse risk.
- Track the FDA’s perspectives on abuse-deterrent IR opioids
- Survey the next wave of technical approaches for IR ADFs
- Identify key trends in opioid abuse worsened by lack of ADFs

Alexander Kraus, Vice President, Business Unit North America, GRUNENTHAL

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5:45 Networking Reception

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| 9:45  | **Gauge the Impact of Inclusion and Exclusion Criteria on HAP Cost and Schedule** | Screen fail rates are profoundly affected by safety lab inclusion and exclusion rates. Criteria for passing the discrimination phase can also influence timelines and the cost of a HAP trial.  
- Discuss the criteria and proposed guidelines to ensure study safety  
- Construct a reasonable schedule for HAP studies based on inclusion criteria  
- Maintain clear lines of communication at all times between CROs, sites and sponsors | Lynn Webster, *Vice President, Scientific Affairs, PRA HEALTH SCIENCES*                                                                                                                                   |
| 10:30 | **Apply Opioid ADF Lessons Toward Stimulants**                         | The success of agonist-based pharmacotherapies for opiates and nicotine has been mirrored in the ability of amphetamine to decrease cocaine use in the animal and human laboratory as well as in clinical trials. Although it is highly unlikely that the FDA would approve an amphetamine-like drug for this indication, a prodrug-based approach may prove more feasible.  
- Detail the construction of prodrugs that function as ADFs  
- Evaluate data from previously approved diet drugs  
- Discuss the utility of drug combinations in decreasing the abuse potential of medications | Paul Czoty, *Associate Professor, Physiology and Pharmacology, WAKE FOREST UNIVERSITY SCHOOL OF MEDICINE*                                                                                               |
| 10:30 | **Networking Break**                                                    |                                                                                                                                                                                                          |                                                                                                            |
| 11:00 | **Match New Developments in the Postmarketing Surveillance of Prescription Drug Abuse** | The turbulent world of abuse-deterrent formulations has been embroiled in controversies regarding heroin abuse rates. This has spurred broader discussions on the goal of abuse-deterrent formulations in general.  
- Clarify the goals of abuse-deterrent formulations  
- Quantify the data on heroin use — is it an unexpected result?  
- Unify our understanding of prescription drug abuse and the role of heroin to explain all available data | Richard Dart, *Director, ROCKY MOUNTAIN POISON AND DRUG CENTER*                                                                                                                                         |
| 11:00 | **Forecast the Development Life Cycles and ROI of New ADF Technologies** | As the larger drug companies enter the ADF field and help drive drug adoption, there will be rising expectations for strong ROI and more investment in new technologies. As technology overall heads toward gastric juice depletion, a review of the most likely upcoming candidates would be worthwhile.  
- Analyze the future of matrix technologies, such as modified oxycodone  
- Focus on combination and prodrug technological breakthroughs  
- Gauge the likelihood of developing prodrug technology that prevents oral overdose | Dan Cohen, *Forum Chair, ABUSE DETERRENT COALITION*                                                                                                                                                        |
| 11:45 | **Analyze the CDC Guidelines for Prescribing Opioids for Chronic Pain**  | Safety pharmacology studies will be relevant at all stages of the development of ADFs. Toxicology professionals must collaborate closely with pharmacology and pharmacokinetic colleagues.  
- Manage timelines for toxicology and safety pharmacology testing  
- Apply lessons from seizure-liability drugs to new ADFs  
- Add toxicology expertise to the development of new opioids | Andrew Barrett, *Senior Director, Scientific Affairs, KEMPHARM*                                                                                                                                             |
| 11:45 | **Provide Toxicology Guidance for New Neurology and Psychiatry Compounds** |                                                                                                                                                                                                          | Mausumee Guha, *Senior Director, Toxicology, MEDIVATION*                                                                                                         |
| 12:30 | Luncheon                                                               |                                                                                                                                                                                                          |                                                                                                            |

“Opioids, such as prescription painkillers, are the leading cause of deaths due to drug overdoses in America, and rising quickly... Nearly 6 people for every 100,000 residents in the United States died of an opioid overdose in 2014.”
—*Time*, June 3, 2016

“After years of relentless growth, the number of opioid prescriptions in the United States is finally falling, the first sustained drop since OxyContin hit the market in 1996. For much of the past two decades, doctors were writing so many prescriptions for the powerful opioid painkillers that, in recent years, there have been enough for every American adult to have a bottle. But for each of the past three years — 2013, 2014 and 2015 — prescriptions have declined, a review of several sources of data shows.”
Thursday, November 3, 2016

1:30

**Optimize Abuse Liability Trial Design for Buprenorphine-Based Products**
When working with drugs aimed at patients who are already in addiction treatment, there are very different considerations from those where your chief concern is to prevent the initial abuse.
- Appreciate the levels of stigma effecting your patients
- Unite dependence management drugs into broader therapeutic regimens
- Accurately compare results across multiple delivery methods

Howard Chilcoat, Head, Epidemiology, INDIVIOR

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**Build an Oxycodone Prodrug with MPAR (Multi-Pill Abuse Resistance) Overdose Protection Technology**

Pf614 and other trypsin-activated BIO-MD™ prodrugs developed by Ensysce Biosciences have inherent abuse deterrence since they are pharmacologically and chemically inert until activation by pancreatic trypsin. Immediate-release (IR) or extended-release (ER) timed activation may be created depending on chemical linkers used to create prodrugs of opioids, stimulants, sedative-hypnotics and other drugs that present challenges for duration of action, abuse-deterrence, solubility or oral bioavailability. Activation can also be limited or stopped by the addition of trypsin inhibitors that control the rate of release of active moieties. These combinations of the BIO-MD™ prodrugs with trypsin inhibitors provide overdose protection of our MPAR products.
- Contrast current and emerging prodrug technologies with other oral, parenteral and nasal abuse-deterrence technologies
- Profile PF614, an extended-release oxycodone prodrug scheduled for Phase 1 clinical trials in 2H2016
- Discuss MPAR overdose protection that has already been demonstrated in a Phase 1 clinical study with PF329, an extended-release hydromorphone prodrug

William Schmidt, CMO, ENSYSCE

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2:15

**Risk Management and Monitoring Plans to Predict Abuse Potential**
Getting the fullest picture of the abuse potential of your drug requires monitoring a diverse array of data through appropriately designed questions and pill-tracking programs. By determining which avenues of abuse are more and less likely, you can make a more convincing presentation to regulatory agencies.
- Remove ambiguity from new pill orders by predicting when refills would normally be requested
- Rank the best pain scales and measuring tools for your questionnaires
- Establish SMQs to seek out adverse events

Lisa Benaise, former Senior Director, Pharmacovigilance, SAREPTA THERAPEUTICS

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**Reorient ADF Development for Non-Analgesic Opioids**
Novel delivery systems for opioids indicated for treatment of opioid dependence offer promising ways to reduce the risks of diversion and abuse. However, ADF guidelines to date are focused primarily on pill-based drug delivery and thus do not readily support a path to ADF labeling for these new formulations. The unique considerations for buprenorphine ADF in treatment of opioid dependence must be taken into account in future guidelines for ADF development.
- Survey the latest developments in novel buprenorphine delivery systems, including implants and injections
- Examine barriers to dispensing products to physicians instead of individuals, including DEA restrictions
- Consider role of key stakeholders in supporting the development of novel buprenorphine delivery systems, including clinicians and insurers

Jonathan Young, General Counsel, Vice President, Policy, BRAEBURN PHARMACEUTICALS

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3:00

**Strengthen Clinical Relevance of Animal Models in Abuse Liability Testing**
The FDA currently requires relatively simple abuse liability testing in animals. Refinement of animal models may enhance translation relevance and predictive ability.
- Use self-administration models in laboratory studies that better reflect clinical features of drug use and medication administration
- Highlight the importance of relevant behavioral models and chronic pharmacotherapy administration
- Broaden consideration of subject factors, including drug use history, sex and polysubstance use

Paul Czoty, Associate Professor, Physiology and Pharmacology, Wake Forest University School of Medicine

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**Review, Anticipate and Model New Technological and Drug Delivery Platforms for Abuse Deterrence**
Analyzing the most recent regulatory performance of ADFs can give a starting point for future expectations and the design of new ADFs. These developments should be reviewed with an eye on upcoming applications that allow for changing drug release rates in order to lower abuse potential and address unmet needs in drug abuse deterrence.
- Evaluate the likelihood of ADFs for solid dosage oral forms
- Take stock of the most promising novel developments of abuse-deterrent molecules
- Build models of success for drug candidates moving forward

Isa Odidi, CEO, INTELLIPHARMACEUTICS

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3:45

Conference Concludes
Registration fees for attending ExL’s 3rd Human Abuse Liability & Abuse-Deterrent Formulations conference:

**EARLY BIRD PRICING**

Register By Friday, September 16, 2016

$1,895

**STANDARD PRICING**

$2,095

**ONSITE PRICING**

$2,195

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