Advancements and Challenges in Abuse Potential Evaluation

Agenda

11 - 12 October 2018
Hyatt Regency, Bethesda, MD

Organized by the Cross-Company Abuse Liability Council (CCALC),
With scientific support from Food and Drug Administration (FDA),
And participation by representatives of FDA and National Institute of Drug Abuse (NIDA)

DAY 1	**Thursday, 11 October 2018**
7:45-8:30	**Breakfast and Registration**
8:30-8:45	**Welcome** Beatriz Rocha (CCALC, Covance) Dominic Chiapperino (FDA/CSS)
	Keynote Speaker(s)
8:45-9:15	Douglas Throckmorton (FDA/CDER)
9:15-9:30	David McCann (NIDA)
	Morning session: Preclinical (Chairs: Carrie Markgraf (Sunovion)and Tom Hudzik (GSK))
9:30-9:50	An evidence-based evaluation of the possible influence of gender on results from drug-discrimination, intravenous self-administration and tolerance/dependence safety pharmacology testing. *Presenter: David Heal (RenaSci)*
	Nonclinical challenges for weakly reinforcing drugs and for physical dependence
9:50-10:10	Partial generalization in drug discrimination: Considerations for interpretation. *Presenter: Nancy Ator, (John Hopkins)*
10:10-10:25	**Morning Break**
10:25-10:55	Study design considerations and thoughts on best practice for nonclinical physical dependence. *Presenter: Thomas Hudzik (GSK)*
10:55-11:25	The value of progressive ratio schedules of reinforcement in abuse potential assessments. *Presenter: Susan Goody (Pfizer)*
11:25-12:00	Panel Discussion: Preclinical Panel: Silvia Calderon (FDA/CSS), Dominic Chiapperino (FDA/CSS), Susan Goody (Pfizer), Nancy Ator (John Hopkins), David White (NIDA) , David Compton (Sanofi), Richard Briscoe (Merck), David Heal (RenaSci), Beatriz Rocha (Covance), Edward Hawkins (FDA/CSS), Carrie Markgraf (Sunovion), Thomas Hudzik (GSK)
12:00-1:00	**Lunch**
	Afternoon Session: Clinical (Chair: Beatrice Setnik (Syneos Health))
	Physical dependence studies—Clinical Considerations
1:00-1:20	Evaluating drug dependency in healthy and patient populations – clinical study design recommendations and translation from preclinical. *Presenter: Katherine Bonson (FDA/CSS)*
1:20-1:30	Pragmatic considerations in designing physical dependency studies in patient and healthy volunteer studies. *Presenter: Beatrice Setnik (Syneos Health)*

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1:30-2:00	Panel discussion: Katherine Bonson (FDA/CSS), Sandra Comer (Columbia University), Reginald Fant (Pinney Associates), Beatrice Setnik (Syneos Health), Beatriz Rocha (Covance) • Best practices for appropriate endpoint selection and frequency of measurements • Interpretation of preclinical data to guide clinical study design • Determining appropriate study durations of exposure and withdrawal periods
	Further discussion of statistics for HAL studies
2:00-2:20	Statistical considerations on pharmacodynamic assessment of human abuse potential studies. *Presenter: Ling Chen (FDA/CSS)*
2:20-2:40	Statistical and regulatory issues in human abuse potential studies. *Presenter: Catherine Mills (Syneos Health)*
2:40-3:00	Panel discussion: Ling Chen (FDA/CSS), Qianyu Dang (FDA/CSS), Catherine Mills (Syneos Health), Beatrice Setnik (Syneos Health) • Best practice for statistical tests on the primary and secondary endpoints • Defining and applying margins; strategies for handling key secondary and secondary endpoints
3:00-3:15	**Afternoon break**
	AEs of interest in clinical studies
3:15-3:30	Regulatory considerations for the collection and presentation of abuse -related adverse events. *Presenter: Shalini Bansil (FDA/CSS)*
3:30-3:45	Defining preferred terms relevant to abuse potential. *Presenter: Beatrice Setnik (Syneos Health)*
3:45-4:00	A systematic approach to monitor misuse, abuse and diversion in clinical trials (MADDERS) *Presenter: Ryan Lanier (Analgesic Solutions)*
4:00-4:15	Abuse liability related AEs – what can we learn from reviewing FDA assessments of recently approved products? *Presenter: Marta Sokolowska*
4:15-4:50	Panel discussion: Shalini Bansil (FDA/CSS), Silvia Calderon (FDA/CSS), Dominic Chiapperino (FDA/ CSS), Ryan Lanier (Analgesic Solutions), Sandra Comer (Columbia University), Marta Sokolowska, Cynthia Arons (Pfizer), Beatrice Setnik (Syneos Health) • Gaining consensus on AEs of interest • Best practices for collection of AEs • Best practices for narration and data presentation
4:50-5:00	**Day 1 Wrap-up** Beatriz Rocha (CCALC, Covance)
5:30-7:00	**Reception** Food and beverage open to all registrants

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Day 2	Friday, Oct 12, 2018
	Evaluating human factors in abuse potential; an exploratory discussion (**Chairs: Cynthia Arons (Pfizer), Marta Sokolowska**)
8:30-8:45	Introductory Remarks: Evaluating Human Factors in the context of abuse potential assessments. *Presenter: Silvia Calderon (FDA/CSS)*
8:45-9:15	Using social science research to explore drug topics: CDER's methods with potential for understanding preferences. *Presenter: Paula Rausch (FDA/OCOMM/CDER)*
9:15-9:45	The intersection between epidemiologic and social media data to investigate emergent drugs of abuse. *Presenter: Nicholas Peiper (RTI)*
9:45-10:15	Patient preferences and health behavior: Are patients voting with their scripts? *Presenter: Juan Marcos Gonzalez (Duke University)*
10:15-10:30	**Morning Break**
10:30-10:50	Drug abuse liability assessment in the time of internet and social media - industry perspective. *Presenter: Marta Sokolowska*
10:50-11:10	Clinical abuse potential assessments: What can we learn from tobacco research. *Presenter: Megan Shram (Altreos Research Partners)*
11:10-11:30	Innovative Approaches to Post-marketing Surveillance. *Presenter: Janetta Iwanicki (RADARS)*
11:30-11:50	Novel approaches to closing the gaps in the current post-market surveillance mosaic. *Presenter: Jody Green (Inflexxion)*
11:50-12:10	Cryptomarket Data for Research and Regulatory Reporting. *Presenter: Michael Gilbert (Booz Allen Hamilton)*
12:10-12:55	Panel Discussion: Paula Rausch (FDA/OCOMM/CDER, Nicholas Peiper (RTI), Megan Shram (Altreos), Juan Marcos Gonzalez (Duke University), Marta Sokolowska, Jody Green (Inflexxion), Janetta Iwanicki (RADARS), Kathryn Aikin (FDA/OPDP/CDER), Cynthia Arons (Pfizer) • How do these methods fit into drug development life-cycle • Can we learn from other research areas • Validation of methods/instruments • Implications for labeling and scheduling • What does the future look like
12:55-1:00	**Conference Wrap-up** Beatriz Rocha
1:00-1:30	**Lunch**