Advancements in Abuse Potential Assessments

- Building on the FDA Draft Guidance for Industry

16 - 17 April 2015

Bethesda North Marriott Hotel & Conference Center, Salon F-G (lobby level)

Organized by the Cross-Company Abuse Liability Council, CCALC,

With scientific support from National Institute on Drug Abuse, NIDA,

And presentations by FDA and NIDA representatives

DAY 1

7:45–8:30	*Registration (Foyer H)*
7:45–8:30	*Breakfast (Foyer)*
8:30–8:45	**I. Welcome** CCALC – Marta Sokolowska (Grunenthal US) FDA – Michael Klein (CSS/FDA)
8:45–9:15	**II. Keynote Speaker** Presenter: Douglas Throckmorton (CDER/FDA)
9:15–9:30	**III. Comments from NIDA** Presenter: Wilson Compton (NIDA)
	IV. Preclinical Section: Chairs: Carrie Markgraf (Merck) and David Compton (Sanofi)
	1. Preclinical Strategy for Evaluation of Novel Mechanism Compounds
9:30–10:00	CSS perspective on the review of preclinical abuse potential data on decision making *Presenter: Silvia Calderon (CSS/FDA)*
10:00–10:30	***Discussion Panel:*** Moderators: Carrie Markgraf and David Compton Panelists: Jane Acri (NIDA), Mary Jeanne Kallman (Covance), Michael Klein, Paul Butler (Pfizer), Beatriz Rocha (Covance)
10:30–10:45	*Coffee Break (Foyer)*
	2. Unique Challenges in Study Designs
10:45–11:00	Addressing challenges in study design for compounds with novel MOA *Presenter: Mary Jeanne Kallman*
11:00–11:15	Use of Intracranial Self-Stimulation Model in Assessing Abuse Potential *Presenter: Steve Negus (Virginia Commonwealth University)*
11:15–11:30	Conditioned Place Preference: Relation to Self-Administration and Predictor of Abuse Potential *Presenter: Christopher Cunningham (Oregon Health & Science University)*

11:30–12:00	***Discussion Panel:*** Moderators: C. Markgraf and D. Compton Panelists: Silvia Calderon, Christopher Cunningham, Thomas Hudzik (AbbVie), Mary Jeanne Kallman, David. McCann (NIDA), Beatriz Rocha, Steve Negus, Greet Teuns (Janssen R&D)
12:00–1:00	*Lunch Break (White Oak Dining Room, lower level)*

3. Evaluation of Biologics

1:00–1:15	Biologics Overview and Potential Roles in Drug Abuse *Presenter: Thomas Hudzik*
1:15–1:30	Should Biologics be evaluated in preclinical abuse liability studies? *Presenter:* Christina De Zafra (Genentech)
2:30–2:00	***Discussion Panel:*** Moderators: Carrie Markgraf and David Compton Panelists: Jane Acri, Paul Butler, David Compton, Christina De Zafra, Thomas Hudzik, LT Joshua Hunt (CSS/FDA), Beatriz Rocha

V. Clinical Section:

Chairs: Beatrice Setnik (INC) and Marta Sokolowska

1. Approaches to identify and classify adverse events and aberrant behaviors related to abuse, misuse and diversion during clinical drug development

2:00–2:15	CSS recommendations for identification and tracking of abuse-related adverse events during clinical drug development. *Presenter: Martin Rusinowitz, (CSS/FDA)*
2:15–2:30	Visualizing patterns of abuse-related adverse events with statistical methods *Presenter: Cynthia Arons (Pfizer)*
2:30–2:45	Review of MADDERS: A system to identify and classify abuse and misuse – related adverse events in clinical trials *Presenter: Nathaniel Katz (Analgesic Solutions)*
2:45–3:00	A proposal for capturing, categorizing, and organizing adverse events of interest in clinical trials for New Drug Applications *Presenter: Beatrice Setnik*
3:00–3:15	Tracking the unknown: challenges with evaluating drug aberrant behaviors in clinical trials *Presenter: Kerri Schoedel (Altreos Consulting)*
3:15–3:30	*Coffee Break (Foyer)*

Panel Discussion:

3:30–4:30	Moderator: Marta Sokolowska Panelists: Cynthia Arons, Jack Henningfield (Pinney Associates), Nathaniel Katz, Sian Ratcliffe (Pfizer), Martin Rusinowitz, Kerri Schoedel, Penny Levin, : Beatrice Setnik
4:30–5:30	*Networking reception (Foyer)*

DAY 2

7:45–8:30	*Registration (Foyer)*
7:45–8:30	*Breakfast (Foyer)*
8:30–8:45	**Welcome: Day 2**
	V. Clinical Section
	2. Statistical Considerations for Human Abuse Potential Studies
8:45–9:00	An overview of regulatory recommendations for statistical approaches to evaluate human abuse potential study data *Presenter: Ling Chen (FDA)*
9:00–9:15	Statistical challenges – Human abuse liability trials *Presenter: Bijan Chakraborty (Algorithme Pharma)*
9:15–9:30	General statistical models to evaluate abuse potential studies *Presenter: Michael Smith (PRA Health Sciences)*
9:30–10:00	*Panel Discussion:* Moderators: Beatrice Setnik Panelists: Bijan Chakraborty, Ling Chen, Michael Smith.
10:00–10:15	*Coffee Break (Foyer)*
	3. **Assessments of Physical Dependence in Clinical Setting**
10:15–10:30	Regulatory perspective in evaluating drug withdrawal symptoms in clinical trials *Presenter: Alicja Lerner (FDA/CSS)*
10:30–10:45	Clinical trial study designs to evaluate drug withdrawal *Presenter: Edward Sellers (DL Global Partners)*
10:45–11:00	A review of measures to evaluate drug withdrawal for CNS-active drugs *Presenter: Marta Sokolowska*
11:00–11:15	Redefining Recreational Drug User Population in Human Abuse Potential Studies: Considerations of Diagnostic Differences between DSM-IV-TR and DSM 5 *Presenter: Talar Hopyan (INC)*
11:15–12:00	***Panel Discussion:***

	Moderators: Beatrice Setnik Panelists: Talar Hopyan, Alicja Lerner, Sian Ratcliffe, Kerri Schoedel, Edward Sellers, Marta Sokolowska, Lynn Webster (PRA Health Sciences)
12:00–1:00	*Lunch Break (White Oak Dining Room, lower level)*
	VI. Post Marketing Section: Chairs: Cynthia Arons and J. David Haddox (Purdue Pharma L.P.)
	Review of alternative approaches to assess drug misuse, abuse, addiction, and death in community setting
1:00–1:15	Observational post-marketing studies to assess abuse in real-world use: an industry perspective *Presenter : Paul Coplan (Purdue Pharma L.P.)*
1:15–1:30	The potential values and limitations of using claims databases. *Presenter : Carl Roland (Pfizer)*
1:30–1:45	Quantifying social media postings. *Presenter : Theresa Cassidy (Inflexxion)*
1:45–2:00	Using IMS data to identify doctor shoppers. *Presenter : M Soledad Cepeda (Janssen R&D)*
2:00–2:15	Crowd sourcing as a way to evaluate drug abuse in the community, *Presenter : Nabarun Dasgupta (Epidemico)*
2:15–2:30	Considering community in assessing drug abuse patterns and trends: perspective from the NIDA Epidemiology Program *Presenter : Moira O'Brien (NIDA)*
2:30–2:45	*Coffee Break (Foyer)*
2:45–4:15	**Panel Discussion:** Moderators: Cynthia Arons and J. David Haddox Panelists: Theresa Cassidy, M. Soledad Cepeda, Paul Coplan, Nabarun Dasgupta, Richard Fanelli (Purdue Pharma L.P.), Moira O'Brien, Carl Roland.
4:15–4:30	***VII. Concluding remarks***