Cardiac Safety Research Consortium

DIA DEVELOP INNOVATE ADVANCE

CSRC/DIA Think Tank:
Enabling Social Listening for Cardiac Safety

FDA White Oak
June 3, 2016

Overview: Postmarketing safety surveillance primarily relies on data from spontaneous adverse event reports, medical literature, and observational databases. Potential limitations of these data sources include potential underreporting, lack of geographic diversity, potential of patients' perspectives being filtered through health care professionals and regulatory agencies, and time lag between event occurrence and discovery.

There is growing interest by safety stakeholders in exploring the use of social media ("social listening") to supplement established approaches for pharmacovigilance. Health information posted online by patients is often publicly available, and thus represents an untapped source of postmarketing safety data that could supplement data from existing sources of cardiac safety information. The purpose of this think tank is to explore current methods of collecting and evaluating social listening data. Representatives from industry, academia, and the FDA will share their perspectives on the topic of social listening and discuss its potential implications in the field of cardiac safety.

8:30 am -9:00 am: Welcome and Introductions

CSRC Introduction	**DIA Introduction**	**Overview of key concepts**
John Finkle, GSK	Raleigh Malik, DIA	Greg Powell, GSK

9:00 am – 10:25 am: Session 1

Review of current safety surveillance methods and overview of social listening
Session chairs: Greg Powell, GSK
Harry Seifert, GSK

Review current safety surveillance methods (Oanh Dang, FDA)
Overview of social listening methods (Nabarun Dasgupta, Epidemico)
Practical examples of social listening for safety (Lorrie Schifano, GSK)
Social listening for cardiac safety research (Bruce Donzanti, Genentech)
Panel Discussion

10:25 am – 10:35 am: Break

10:35 am – 12:00 pm: Session 2

Practical considerations of social listening for cardiac safety – why this is valuable
Session chair: Melissa Truffa, Abbvie

Patient perspective (Sally Okun- PatientsLikeMe)
Regulatory perspective MHRA (Phil Tregunno, MHRA)
Regulatory perspective FDA (speaker TBD)
Pharma perspective (Mondira Bhattacharya- AbbVie)
Panel Discussion

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12:00 pm- 12:45 pm ***Lunch***

12:45 pm – 2:10 pm: ***Session 3***

What evidence is needed to inform use of social listening for cardiac safety
Session chair: John van Stekelenborg, Janssen

Social Media-people sharing CV experiences (Amir Lewkowics, Inspire)
Academia point of view (Mitchell Krucoff, Duke Clinical Research Institute)
Cardiac risk factors (Kevin Campbell, UNC)
Industry point of view (John van Stekelenborg, Janssen)
Panel Discussion

2:10 pm – 2:30 pm: ***Closing remarks***
Harry Seifert, GSK

This think tank is hosted by the Cardiac Safety Education Collaborative (CSEC)—a partnership between DIA and the Cardiac Safety Research Consortium (CSRC), an FDA and Duke University public-private partnership. The objective of the CSEC is to advance open dialogue of issues related to cardiac safety that represent barriers to medical product development, or issues that constitute limitations in current regulatory science. This think tank is part of the CSEC Signature Program that will span the course of a year and includes a webinar and various publications.