



# Mini-Sentinel from Vision to Reality: A Patient Representative's Perspective

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# Disclosures

- FDA Patient Representative
- Mini-Sentinel National Planning Board
- Clinical Trials Transformation Initiative Steering Committee
- PFO Research Foundation, President and CEO
- Alliance for Headache Disorder Advocacy, Board Member
- American College of Cardiology Foundation Patient-Centered Care Shared-Decision Making Workgroup

# Patients Asleep at the Wheel

Most of us are not thinking about post-market safety and surveillance until we (or perhaps loved ones) experience a problem with a product or suffer an illness treated with novel therapies.



## Most Patients and Consumers Have Little, If Any, Understanding of How Products are Monitored

- What happens when reports get filed in AERS?
- How will FDA decide when to launch a Mini-Sentinel query?
- What happens if a signal is detected?
  - Investigators look at causality, impact, preventability
  - Patients wonder “will I lose access to the therapy that has been beneficial to me, or if I am harmed will other patients be protected from the same possible outcome?”

# Making Sense of It All

- Moving from passive to active surveillance; access to 126,000,000 health records and 3 billion dispensings
- Who should interpret scientific information and translate it to patients in a meaningful way?
- How does information get communicated to the public?
- What does a signal mean to me?
- Let's be mindful in what we ask of Mini-Sentinel investigators - they are scientists, not health literacy experts

# Personal Observations on Mini-Sentinel

- Leaders and partners should be applauded for overcoming huge challenges in collaboration and governance
- Acted with integrity and transparency
- Showed thoughtfulness on topics of interest to patients
  - Conflict of interest
  - Protected data
- Tasks completed ahead of schedule

# Kudos to the Mini-Sentinel Partner Organizations

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# Where do we go from here as patients?

- Ask ourselves if we have a good understanding of risk/benefit and uncertainty
- Think carefully about what information is meaningful and how we would like it to be communicated to us
- Continue the dialogue with Mini-Sentinel leaders and FDA about public confidence in Sentinel and the “handshake” with the patient community