FDA Patient Related Engagement: Enhancing patient centeredness in research Implementation

Our #AskCUE Twitter Chat is TODAY! Starting at 1pm EST! Join us as we discuss patient engagement at the FDA! @FDA_Patient_Net @GuidelinesNA pic.twitter.com/LLjDyR9N8S

@CUE United4Evidence · A YEAR AGO

Today is the day! Join us for our #AskCUE TwitterChat w @FDA_Patient_Net @1PM EST! #PatientEngagement #ConsumersUnited

@CUE United4Evidence · A YEAR AGO

Just 30 more minutes until our #AskCUE TwitterChat with @FDA_Patient_Net on patient engagement at the FDA! @VinayPrasad82 @AnnieAppleseed

@CUE United4Evidence · A YEAR AGO
Five minutes away from the start of our #AskCUE TwitterChat with @FDA_Patient_Net! Check out the team to see who we’ll be talking to: pic.twitter.com/0D4aTLIKaZ

Welcome to our #AskCUE TwitterChat on #PatientEngagement at the FDA! We’d like to start off by thanking @FDA_Patient_Net for co-hosting!

Chapter 1: FDA Engagement with Patient

@FDA_Patient_Net How, specifically, does the fDA engage patients? #AskCUE

FDA’s Patient Rep Program, Patient Network, device Patient Preference Initiative, Patient-Focused Drug Development; #AskCUE twitter.com/United4Evidenc...
T1A1b: To learn more about our Programs visit go.usa.gov/x8m3F. Patients can participate in Advisory Committee Panels #AskCUE

T1A1c: Public workshops, Meetings & Open Public Hearing Testimonies. Visit go.usa.gov/x8maE #AskCUE

T1Q2. @FDA_Patient_Net At which stages of the regulatory process do patients collaborate? #AskCUE @GuidelinesNA

T1A2: From various points along the medical product development lifecycle through the post-marketing process #AskCUE pic.twitter.com/L2ktnBnFYL
CUE @United4Evidence

#T1Q3. @FDA_Patient_Net What are some of the upcoming programs that FDA plans to initiate to expand patient engagement? #AskCUE

A YEAR AGO

FDA Patient Network @FDA_Patient_Net

T1A3: FDA’s patient engagement initiative go.usa.gov/x8Udb; Device’s Patient Engagement Advisory Committee go.usa.gov/x8UdK #AskCUE twitter.com/United4Evidence...

A YEAR AGO

CUE @United4Evidence

@USCochrane T1Q3b FDA had lots of places for the public to participate in regulatory process. Where will I have the most impact? #askcue

A YEAR AGO

FDA Patient Network @FDA_Patient_Net

T1A3b: Upcoming Patient-Focused Drug Development Initiative activities go.usa.gov/x8mcK & extended meetings go.usa.gov/x8mhs #AskCUE

A YEAR AGO

CUE @United4Evidence

T1Q3C: And will I have to declare potential conflicts of interest at any/all of the opportunities? #AskCUE twitter.com/uscochrane/status/811... twitter.com/mnx/status/811...

A YEAR AGO

CUE @United4Evidence

T1Q4. @FDA_Patient_Net Where can patients go to find a list of FDA advisory panels/public meetings? #AskCUE @GuidelinesNA @NC4HR

A YEAR AGO
T1A4: FDA’s Patient Network calendar of public meetings page to find a complete list of FDA public meetings go.usa.gov/x8mc5 #AskCUE pic.twitter.com/FDrL9Osd5G

T1Q5. @FDA_Patient_Net What site can patients visit to submit public comments? #AskCUE @hhask @katherinekleon

T1A5: FDA’s Patient Network features opportunities that may be important for patients to comment go.usa.gov/x8nJj #AskCUE pic.twitter.com/g7Zppg9dT
Chapter 2: Patient Representative Program

T1Q6. @FDA_Patient_Net How can patients learn about FDA news that might interest them? #AskCUE @VinayPrasad82 @ncl_tweets @NC4HR

T1A6: By subscribing to the biweekly Patient Network Newsletter. To subscribe & see previous issues go to go.usa.gov/xKe52 #AskCUE pic.twitter.com/ehn7PHijDH

Chapter 2: Patient Representative Program

CUE @United4Evidence

Now to learn a little bit more about the Patient Representative Program itself! #AskCUE @FDA_Patient_Net

T2Q1. @FDA_Patient_Net What is the FDA Patient Representative Program? #AskCUE

A YEAR AGO
T2A1: A prgrm that brings pt prspctvs to FDA as decisions are made for regulating drugs, biologics, devices go.usa.gov/x8Uv9 #AskCUE twitter.com/United4Evidenc...

T2A1b: Apprx 200 Patient Reps serve in the Prgrm & participate on FDA Advisory Committee & Divisional mtngs. go.usa.gov/x8maH #AskCUE pic.twitter.com/rzswTVmSBM

T2Q2. @FDA_Patient_Net How are FDA Patient Representatives selected to serve on an advisory panel for a specific meeting? #AskCUE

T2A2: Selections are based on Patient Reps w/the most appropriate experience of disease /condition that’s of topic at the meeting #AskCUE twitter.com/United4Evidenc...

T2Q3. @FDA_Patient_Net Does the FDA have specific criteria they use for recruitment? #AskCUE
T2A3: FDA recruits as needed and follows key criteria to identify and select appropriate Patient Representatives #AskCUE twitter.com/United4Evidence...

T2A3b: Considerations include disease/condition/advocacy experience, communication skills, conflict of interest issues #AskCUE twitter.com/United4Evidence...

T2A3c: For more info on our criteria, please visit go.usa.gov/x8maf #AskCUE twitter.com/United4Evidence...

On to the next topic now! Let's discuss conflicts of interest! @FDA_Patient_Net @AnnieAppleseed #AskCUE

Chapter 3: Conflicts of Interest

T3Q1. @FDA_Patient_Net Many patient groups are at least partly funded by industry. How do you guard against COI among patients? #askCUE

T3A1: FDA analysts conduct comprehensive conflict-of-interest screening for pts as they engage with FDA go.usa.gov/x8Uvp #AskCUE twitter.com/United4Evidence...
Chapter 4: Capacity Building for Patients

CUE @United4Evidence

T4Q1. @FDA_Patient_Net What kind of resources does the FDA offer to its Patient representatives? #AskCUE

A YEAR AGO
T4A1: FDA 101 training, a 2-day workshop on FDA regulations & quarterly webinars. To view these webinars; go.usa.gov/x8UwK #AskCUE pic.twitter.com/GWq4RqjXUw

CUE @United4Evidence

T4Q2. @FDA_Patient_Net What areas do patients need to have more knowledge in? #AskCUE

FDA Patient Network @FDA_Patient_Net

T4A2: Understanding dvlpmt lifecycles for medical prdcts, rsrch & trtmnt in their disease/condt of interest; go.usa.gov/x8mag #AskCUE twitter.com/United4Evidenc...

FDA Patient Network @FDA_Patient_Net

T4A2b: Clinical trials research enterprise, and how to better engage with FDA go.usa.gov/x8maK #AskCUE twitter.com/United4Evidenc...
Wow an hour up already. Thank you @FDA_Patient_Net for your time. @AnnieAppleseed @mnx @UScochrane @jheyward14 Thanks! #AskCUE

A YEAR AGO

Thought Stimulating Questions

@FDA_Patient_Net Many patients are involved in the research process. How can we get them to also engage in research implementation? #AskCUE

A YEAR AGO

FDA had lots of places for the public to participate in the regulatory process. Where will I have the most impact? #askcue

A YEAR AGO

Does this mean you look for such activity when reviewing products for approval? #AskCUE

twitter.com/fda_patient_ne...

A YEAR AGO

And will I have to declare potential conflicts of interest at any/all of the opportunities? #AskCUE

twitter.com/uscochrane/sta...

A YEAR AGO

Patients are arguably well-integrated into the research process. At FDA, are they integrated into the regulatory process? How? #askcue

A YEAR AGO
FDA Patient Related Engagement: Enhancing patient centeredness in research Implementation

Cochrane US @UScochrane

FDA: can you give an example of where patients have made a difference in an FDA decision? #askcue

A YEAR AGO

Cochrane US @UScochrane

I really want to contribute to FDA decision-making, Tell me what to do so I can make a difference. #askcue

A YEAR AGO

Nicole Fusco @napcat87

@United4Evidence @FDA_Patient_Net @VinayPrasad82 @ncl_tweets @NC4HR Where should patients go to find reliable research evidence? #AskCUE

A YEAR AGO

CUE @United4Evidence

Good point @AnnieAppleseed! @FDA_Patient_Net How far in advance are consumers/patients notified about meeting topics/info? #AskCUE

A YEAR AGO

Cochrane US @UScochrane

The media reports that pt input has not had an effect in some regulatory decisions (eg, muscular dystrophy). Help me understand. #askcue

A YEAR AGO

Cochrane US @UScochrane

@FDA_Patient_Net It's discouraging if pts assess the evidence & then a potential CoI leads to a decision that's not evidence-based #askcue

A YEAR AGO
Jamie
@jheyward14

#askcue as w/ muscular dyst drug, some pt gps have industry funds, others don't. how to decide which pts to hear from? @FDA_Patient_Network

A YEAR AGO

Jamie
@jheyward14

@FDA_Patient_Net when will enforcement of the final rule begin? #AskCUE

A YEAR AGO

Cochrane US
@UScochrane

@FDA_Patient_Net but how do you enforce the rules? #askcue

A YEAR AGO

Cochrane US
@UScochrane

@FDA_Patient_Net Does the FDA offer resources to patient reps? If yes, does this include reimbursement for time? #askcue

A YEAR AGO

Mary Nix
@mnx

@FDA_Patient_Net Is there an easier to read version of that comprehensive COI policy? #plainlanguage #AskCUE twitter.com/fda_patient_ne...

A YEAR AGO

Cochrane US
@UScochrane

@FDA_Patient_Net Do pts need more knowledge in specific areas to contribute maximally? If yes, what areas/topics would be useful? #AskCUE

A YEAR AGO
Conclusion
Thanks for chatting with us today. If you should have additional questions/comments, please email us at PatientNetwork@fda.hhs.gov #AskCUE