

by CUE Cochrane USA 10 months ago

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](#)

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[@United4Evidence](#)

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

A YEAR AGO



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

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

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

A YEAR AGO

Chapter 1: FDA Engagement with Patient



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T1Q1. [@FDA_Patient_Net](#) How, specifically, does the fDA engage patients? [#AskCUE](#)

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FDA Patient Network
[@FDA_Patient_Net](#)

T1A1: FDA's Patient Rep Program, Patient Network, device Patient Preference Initiative, Patient-Focused Drug Development; [#AskCUE twitter.com/United4Evidenc...](#)

A YEAR AGO



FDA Patient Network

@FDA_Patient_Net

T1A1b: To learn more about our Programs visit go.usa.gov/x8m3F. Patients can participate in Advisory Committee Panels #AskCUE



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FDA Patient Network

@FDA_Patient_Net

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



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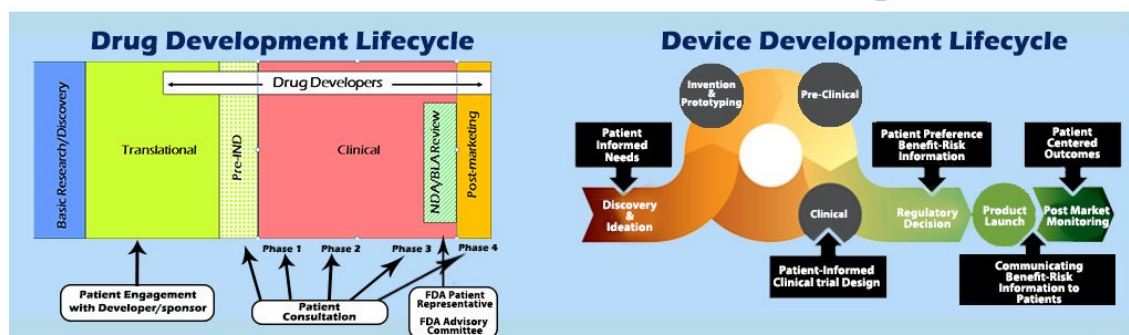
T1Q2. @FDA_Patient_Net At which stages of the regulatory process do patients collaborate? #AskCUE @GuidelinesNA



A YEAR AGO



Patient Involvement During Medical Product Development



from the FDA Office of Health and Constituent Affairs

for more information visit: www.fda.gov/forpatients

T1A2: From various points along the medical product development lifecycle through the post-marketing process #AskCUE pic.twitter.com/L2ktnBnFYl



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@United4Evidence

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



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**FDA Patient Network**

@FDA_Patient_Net

T1A3: FDA's pt engagement initiative go.usa.gov/x8Udb; Device's Patient Engagement Advsry Cmmmtt go.usa.gov/x8UdK #AskCUE [twitter.com/United4Evidence...](https://twitter.com/United4Evidence)



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@United4Evidence

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



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**FDA Patient Network**

@FDA_Patient_Net

T1A3b: Upcoming Patient-Focused Drg Dvlpmnt Initiative activities go.usa.gov/x8mcK & ext-led mtngs go.usa.gov/x8mhs #AskCUE



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@United4Evidence

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



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



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Patients & consumers can find a list of FDA advisory panels and public meetings at:
<http://go.usa.gov/x8nuu>

for more information visit: www.fda.gov/forpatients

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

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

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Your Opinion Matters!

from the FDA Office of Health and Constituent Affairs

On regulations.gov you can find, read, and comment on FDA draft guidances and other FDA related documents. Your comments can make a difference and may impact the outcomes of FDA regulatory policy. Share your knowledge and experience and make your voice count.

SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

Submit your input today **Search**

for more information visit: www.fda.gov/forpatients

T1A5: FDA's Patient Network features opportunities that may be important for patients to comment go.usa.gov/x8nJj #AskCUE pic.twitter.com/gZ7Zppg9dT

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



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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



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Chapter 2: Patient Representative Program



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



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



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FDA Patient Network
@FDA_Patient_Net

T2A1: A prgrm that brings pt prspctvs to FDA as decisions are made for regulating drugs, biologics, devices [go.usa.gov/x8Uv9](https://www.fda.gov/x8Uv9) #AskCUE [twitter.com/United4Evidenc...](https://twitter.com/United4Evidence)

A YEAR AGO



Patient Representative Program



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

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

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FDA Patient Network
@FDA_Patient_Net

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...](https://twitter.com/United4Evidence)

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T2Q3. @FDA_Patient_Net Does the FDA have specific criteria they use for recruitment? #AskCUE

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**FDA Patient Network**

@FDA_Patient_Net

T2A3: FDA recruits as needed and follows key criteria to identify and select appropriate Patient Representatives [#AskCUE](#) [twitter.com/United4Evidenc...](#)



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**FDA Patient Network**

@FDA_Patient_Net

T2A3b: Considerations include disease/condition/advocacy experience, communication skills, conflict of interest issues [#AskCUE](#) [twitter.com/United4Evidenc...](#)



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**FDA Patient Network**

@FDA_Patient_Net

T2A3c: For more info on our criteria, please visit [go.usa.gov/x8maf](#) [#AskCUE](#) [twitter.com/United4Evidenc...](#)



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@United4Evidence

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



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Chapter 3: Conflicts of Interest

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



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**FDA Patient Network**

@FDA_Patient_Net

T3A1: FDA analysts conduct comprehensive conflict-of-interest screening for pts as they engage with FDA [go.usa.gov/x8Uvp](#) [#AskCUE](#) [twitter.com/United4Evidenc...](#)



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@United4Evidence

T3Q2. [@FDA_Patient_Net](#) [ClinicalTrials.gov](#) sets rules for transp res reporting. How 2 make sure that companies adhere to these? [#AskCUE](#)



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**FDA Patient Network**

@FDA_Patient_Net

T3A2: FDA issued a final rule that sets strds for reprting data collected during the listed clinical trials [go.usa.gov/x8mcy](#) [#AskCUE](#) [twitter.com/United4Evidenc...](#)



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Chapter4: Capacity Building for Patients

**CUE**

@United4Evidence

Last two questions on capacity building for patients [#AskCUE](#) [@FDA_Patient_Net](#)



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**CUE**

@United4Evidence

T4Q1. [@FDA_Patient_Net](#) What kind of resources does the fDA offer to its Patient representatives? [#AskCUE](#)



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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

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

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@FDA_Patient_Net

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

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@FDA_Patient_Net

T4A2b: Clinical trials research enterprise, and how to better engage with FDA
go.usa.gov/x8maK #AskCUE twitter.com/United4Evidenc...

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**CUE**

@United4Evidence

Wow an hour up already. Thank you @FDA_Patient_Net for your time. @AnnieAppleseed @mnx @UScochrane @jheyward14 Thanks! #AskCUE



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Thought Stimulating Questions

**Nicole Fusco**

@napcat87

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



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**Cochrane US**

@UScochrane

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



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**Mary Nix**

@mnx

Does this mean you look for such activity when reviewing products for approval? #AskCUE twitter.com/fda_patient_ne...



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**Mary Nix**

@mnx

And will I have to declare potential conflicts of interest at any/all of the opportunities? #AskCUE twitter.com/uscochrane/sta...



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**Cochrane US**

@UScochrane

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



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Cochrane US
@UScochrane

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

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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](#)

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@United4Evidence

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

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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](#)

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@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](#)

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**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



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**Cochrane US**

@UScochrane

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



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**Cochrane US**

@UScochrane

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



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**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...



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**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



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@FDA_Patient_Net Does that mean that only patient groups are screened for CoI then?
#AskCUE



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What would you like to see change on their part to improve patient engagement? #AskCUE
@AnnieAppleseed @FDA_Patient_Net



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Jamie
@jheyward14

@FDA_Patient_Net Do you prefer consumers who have experience on research/research implementation panels? #AskCUE [twitter.com/United4Evidenc...](https://twitter.com/United4Evidence)



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@UScochrane

What is the role of diversity? #AskCUE @FDA_Patients_Net [twitter.com/FDA_Patient_Ne...](https://twitter.com/FDA_Patient_Net)



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Cochrane US
@UScochrane

@FDA_Patient_Net How does FDA ensure pt diversity on its cmtees? Is achieving pt diversity easier/arder than fr other stakehldrs? #askcue



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Jimmy Le
@jtoanle

#FDA and some considerations when it comes to addressing #diversity. What a great twitter chat #AskCUE [twitter.com/FDA_Patient_Ne...](https://twitter.com/FDA_Patient_Net)



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Conclusion

**FDA Patient Network**

@FDA_Patient_Net

Thanks for chatting with us today. If you should have additional questions/comments, please email us at PatientNetwork@fda.hhs.gov [#AskCUE](#)



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