

Center for Drug Evaluation and Research (CDER)
Virtual Public Meeting on Patient-Focused Drug Development for Long COVID
US Food and Drug Administration
Tuesday, April 25, 2023

LIVE WEBCAST:

English: <https://fda.yorkcast.com/webcast/Play/4eba453a2412474e98fff1fabcc63ac51d>
Spanish: <https://fda.yorkcast.com/webcast/Play/0385884d5655420fabd3a55a237926691d>

AGENDA

- | | |
|---------------------|--|
| 10:00 – 10:05 am | Welcome
Robyn Bent, R.N., M.S.
<i>Director of Patient-Focused Drug Development, Office of the Center Director (OCD),
Center for Drug Evaluation and Research (CDER), FDA</i> |
| 10:05 – 10:10 am | Opening Remarks
Rachel L. Levine, M.D.
<i>Admiral, U.S. Public Health Service
Assistant Secretary for Health, U.S. Department of Health and Human Services</i> |
| 10:10 – 10:20 am | Overview of FDA’s Patient-Focused Drug Development Initiative
Theresa Mullin, Ph.D.
<i>Associate Center Director for Strategic Initiatives, FDA</i> |
| 10:20 – 10:30 am | Background on Long COVID
Hilary Marston, M.D., M.P.H.
<i>Chief Medical Officer, FDA</i> |
| 10:30 – 10:40 am | Overview of Discussion Format
Robyn Bent, R.N., M.S.
<i>OCD, CDER, FDA</i> |
| 10:40 – 11:10 am | Topic 1: Health Effects and Daily Impacts
A panel of patients and patient representatives will provide comments to start the discussion on health effects and daily impacts of Long COVID. |
| 11:10 am – 12:15 pm | Large-Group Facilitated Discussion on Topic 1
Patients and patient representatives in the audience are invited to add to the dialogue. |
| 12:15 – 12:45 pm | Break |
| 12:45 – 1:15 pm | Topic 2: Current Approaches to Treatment
A panel of patients and patient representatives will provide comments to start the discussion on current approaches to treatment for Long COVID. |
| 1:15 – 2:20 pm | Large-Group Facilitated Discussion on Topic 2
Patients and patient representatives in the audience are invited to add to the dialogue. |

2:20 – 2:30 pm	Break
2:30 – 3:00 pm	Topic 3: Clinical Trials A panel of patients and patient representatives will provide comments to start the discussion on clinical trials related to Long COVID.
3:00 – 3:55 pm	Large-Group Facilitated Discussion on Topic 3 Patients and patient representatives in the audience are invited to add to the dialogue.
3:55 – 4:00 pm	Closing Remarks Michael Iademarco, M.D., M.P.H. <i>Rear Admiral and Assistant Surgeon General, U.S. Public Health Service</i> <i>Deputy Assistant Secretary for Science and Medicine, U.S. Department of Health and Human Services</i>

DISCUSSION QUESTIONS

Topic 1: Health effects and daily impacts that matter most to patients

1. Which **symptoms** of Long COVID have the most significant impact on your life? (Examples may include pain, brain fog, fatigue, heart palpitations, recurring blood clots, depression, or anxiety).
2. Are there **specific activities** that are important to you that you cannot do at all or as fully as you would like because of your Long COVID? (Examples may include reading, sleeping, or exercising).
 - a. Is there a particular impact of Long COVID (such as need to work a reduced work schedule, inability to complete daily tasks, anxiety, or depression) that worries you? If so, what worries you most?
3. How has your Long COVID changed from original diagnosis to now (have you noticed differences in severity, change in symptoms)?

Topic 2: Patients' perspectives on current approaches to treatment

1. **What are you currently doing** to treat or manage your Long COVID? (Examples may include prescription medicines, over-the-counter products, nutritional supplements, and other therapies including non-drug therapies such as pulmonary rehabilitation, aerobic exercises, or diet modifications).
 - a. Has your treatment regimen changed over time, and why?
 - b. What factors went into your decision making when it came to selecting a course of management for your Long COVID?
2. Would you say your Long COVID today is well-managed? Please explain.
3. Assuming there is no complete cure for your Long COVID, what specific things would you look for in an **ideal treatment** for your Long COVID?

- a. Is there a particular symptom of Long COVID (such as fatigue, brain fog, or loss of sense of smell/taste) that you would prioritize for treatment? If so, which symptom would you prioritize?
- b. What would you consider a successful treatment outcome?

Topic 3: Patients' perspectives on clinical trials for Long COVID

1. If you considered participating or have participated in a clinical trial for Long COVID, please tell us about your experience.
 - a. What factors (if any) of the clinical trial **enabled** you to participate?
 - b. What factors (if any) of the clinical trial made it **more difficult** for you to participate?
2. How would the following factors weigh into your decision if you were considering participating in a clinical trial?
 - a. **The clinical trial intervention** (Examples may include side effects of the medical intervention, how the intervention is administered etc.).
 - b. **The logistics of the clinical trial** (Examples may include the duration of the trial, whether the trial is fully remote or requires clinic visits, the number of in-person clinic visits required, distance from home to clinic site, or whether you might receive a placebo or not).
3. What **outcomes** for Long COVID are most important to measure in a trial setting? (Examples may include reduction in pain, brain fog, fatigue, or other aspects; or improvement in your ability to perform daily activities such as reading, sleeping, or exercising)

SUBMIT A COMMENT TO THE PUBLIC DOCKET

We encourage participants to submit written comments to the public docket by June 26, 2023:

<https://www.regulations.gov/document/FDA-2023-N-0363-0001> or visit www.regulations.gov and search for FDA-2023-N-0363-0001.