ASPR TRACIE Technical Assistance Request

Request Receipt Date (by ASPR TRACIE): 9 September 2021
Response Date: 10 September 2021
Type of TA Request: Standard

Request:

ASPR TRACIE received a request for information about whether healthcare providers were required to fill out MedWatch forms to document doses of Bamlanivimab that were administered to patients (even if they did not have adverse effects).

Response:

The ASPR TRACIE Team reached out to our points of contact at the U.S. Food and Drug Administration (FDA), and they provided the following response:

> Thank you for reaching out to the FDA with regards to completing a MedWatch report relating to the use of Bamlanivimab. The FDA Center for Drug Evaluation and Research (CDER)/Office of Surveillance and Epidemiology reviewed the language in the Bamlanivimab Fact Sheet which states, "The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event." It appears that there was no serious adverse events for these particular patients and therefore the requestor would not need to complete a MedWatch form with the FDA.
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> While only medication error and serious adverse event reports need to be reported through MedWatch, there was language in the Fact Sheet regarding the reporting of "therapeutics information and utilization data" to HHS (not FDA) stating "Healthcare facilities and providers must report therapeutics information and utilization data through HHS Protect, Teletracking or National Healthcare Safety Network (NHSN) as directed by the U.S. Department of Health and Human Services."

With regards to FDA's statement about reaching out to HHS, the ASPR TRACIE Team followed up with the appropriate contacts and they stated that the utilization/inventory reporting has fully switched to HHS Protect from NHSN.

Please contact the therapeutics team directly at the following email address: COVID19.Therapeutics@hhs.gov. They should be able to further assist requestors with regards to reporting therapeutics information and utilization data. In addition, the other resource box requestors may contact for general HHS Protect questions is: Protect-ServiceDesk@hhs.gov.