Changes to the Study Data Technical Conformance Guide Special Edition v5.2 – Published May 12, 2023

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These slides are supplemental information to the Study Data Technical Conformance Guide and the Standardized Study Data Guidance

End of the COVID-19 PHE and the Impact on the SEND Requirement

Expiration of the COVID-19 PHE and SEND

- The federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, expired at the end of the day on May 11, 2023.
- For the duration of the COVID-19 PHE, SEND was not required to be submitted to commercial INDs with indications specific to COVID-19 (only required with the marketing application).
- This temporary modification to the SEND requirement expired with the expiration of the HHS declared COVID-19 PHE.

Study Data Standards Resources | FDA

Study Data Technical Conformance Guide

4.1.4.7 Modification of Requirements During Specific Public Health Emergencies Declared by the Secretary of HHS

4.1.4.7.1 SEND Requirements During the COVID-19 Public Health Emergency

HHS Declared Public Health Emergency Reference:
There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[45]

Impacted Electronic Data Standard(s) and submission type(s):
The Standard for Exchange of Nonclinical Data (SEND) for commercial INDs submitted to CDER.

Rationale and Data Standards Requirement
Datasets for nonclinical studies that can be modeled in an FDA-supported Standard for Exchange of Nonclinical Data (SEND) Implementation Guide (SENDIG) version and were initiated after an applicable SEND implementation date outlined in the FDA Data Standards Catalog are required to be submitted in SEND format. However, for the duration of the COVID-19 public health emergency, to help prevent delays in the initiation of clinical trials for products with a proposed indication to diagnose, cure, mitigate, treat, or prevent COVID-19 (COVID-19 specific indications), FDA will not require these datasets in SEND format until the time of submission of a marketing application for products with COVID-19 specific indications. For further information and resources including the guidance for industry, *Providing Regulatory Submissions In Electronic Format – Standardized Study Data*, refer to the following website: https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber.

To help simplify submissions for products with COVID-19 specific indications under commercial IND development that currently do not have SEND datasets available for a nonclinical study, FDA recommends that a simplified ts.xpt file be submitted with each nonclinical study requiring SEND, as outlined in the FDA Data Standards Catalog (https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources). The simplified ts.xpt file will help facilitate acceptance of the IND submission at the electronic gateway. The ts.xpt file should include the use of the null value (i.e.,

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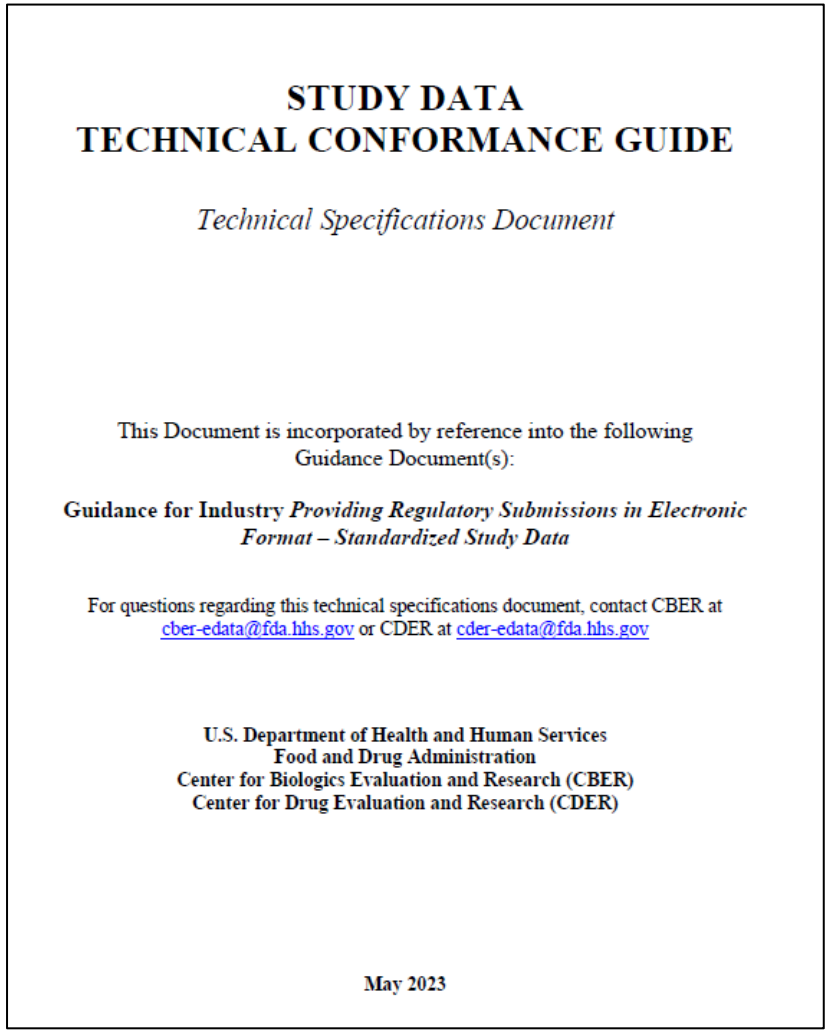


STUDY DATA
TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry ***Providing Regulatory Submissions in Electronic Format – Standardized Study Data***

For questions regarding this technical specifications document, contact CBER at cber-edata@fda.hhs.gov or CDER at cder-edata@fda.hhs.gov

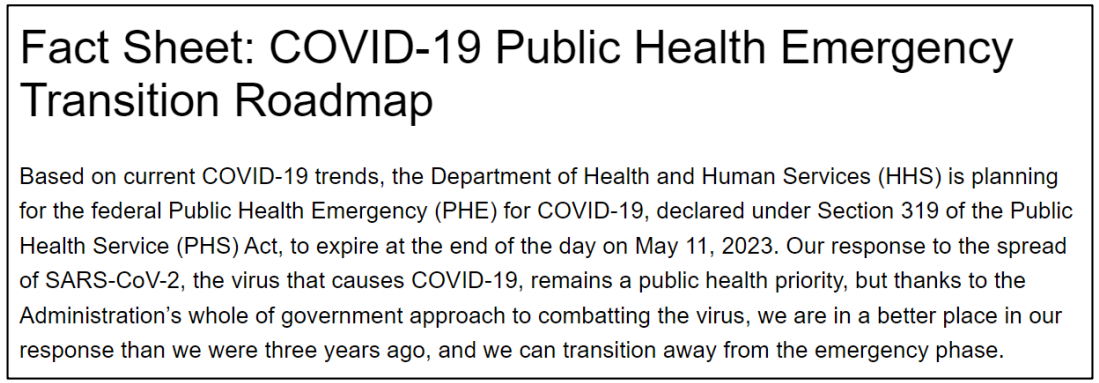
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)

May 2023

- A 180-Day "Wind-Down" period will be given to allow for an orderly transition back to the SEND requirement for COVID-19 related applications under commercial IND.
- Will allow for sponsors to complete studies in progress and once again plan for the SEND requirement.
- Sponsors may submit SEND for these applications at any time but will be required again on November 8, 2023 (submission date).

Expiration of the COVID-19 PHE

During the COVID-19 pandemic, FDA issued more than 80 COVID-19-related guidances and CDER modified the SEND requirement for commercial IND submissions with COVID-19 specific indications.



Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023. Our response to the spread of SARS-CoV-2, the virus that causes COVID-19, remains a public health priority, but thanks to the Administration's whole of government approach to combatting the virus, we are in a better place in our response than we were three years ago, and we can transition away from the emergency phase.

Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap | HHS.gov

Guidance Documents Related to Coronavirus Disease 2019 (COVID-19):
Federal Register /Vol. 88, No. 48 /Monday, March 13, 2023 /Notices

https://www.govinfo.gov/content/pkg/FR-2023-03-13/pdf/2023-05094.pdf

Some guidances allowing for a "wind-down" period.

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4.1.4.7 Modification of Requirements During Specific Public Health Emergencies Declared by the Secretary of HHS

4.1.4.7.1 SEND Requirements During the COVID-19 Public Health Emergency

[Notification of PHE Expiration] CDER's allowance for specific modifications to the SEND requirements during the COVID-19 Public Health Emergency (PHE) expired at the end of the day on May 11, 2023, with the expiration of the COVID-19 PHE declared by the HHS Secretary in accordance with section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)). Information about the specific modifications to the SEND requirements that were permitted during the COVID-19 PHE can be found in Appendix H.

Certain circumstances that were specific to the COVID-19 PHE warrant the allowance of additional time to transition from the policies adopted during the COVID-19 PHE to the reinstatement of the SEND requirement for commercial INDs. To allow for a wind-down period, SEND will not be required to be submitted for commercial INDs with COVID-19 indications for an additional 180 days after the expiration of the COVID-19 PHE (i.e., through November 7, 2023). A simplified ts.xpt file may continue to be used as needed for the additional 180 days, until November 8, 2023. As a reminder, SEND is required at the time of submission of a marketing application for products with COVID-19 specific indications, even if SEND was not submitted under the commercial IND.

As was the case during the COVID-19 PHE, cross-referencing nonclinical studies submitted to a commercial IND for a COVID-19 indication does not obviate the requirement of SEND for a commercial IND for a non-COVID-19 indication.

- A 180-Day "Wind-Down" period will be given to allow for an orderly transition back to the SEND requirement for COVID-19 related applications.
- SEND has been and will continue to be required for all COVID-19 related marketing applications (regardless of whether SEND was submitted under the IND).
- Sponsors may not cross-reference to a COVID-19 related IND application to avoid the SEND requirement when submitting an application for a different indication (i.e., non-COVID-19 related).

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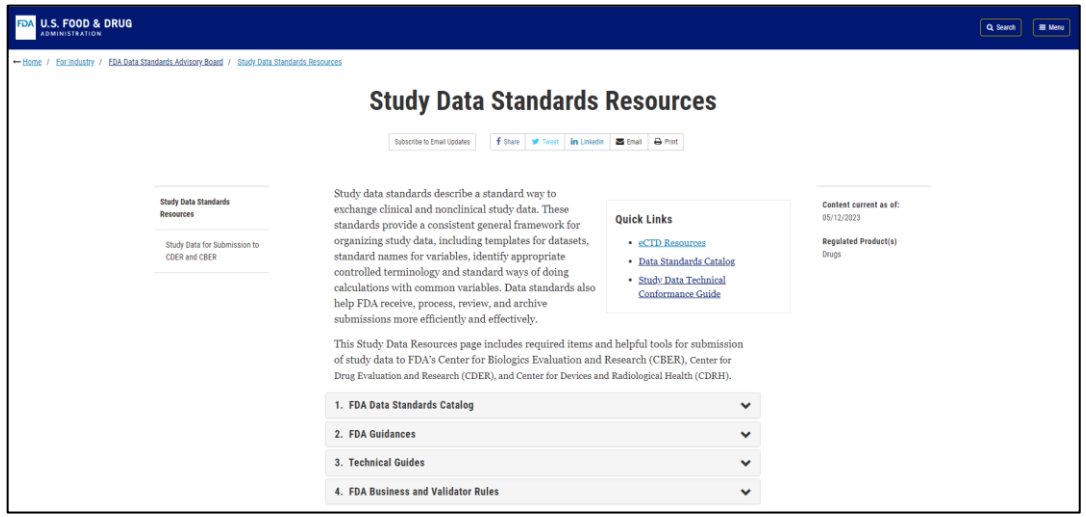
Appendix H: HHS Declared Public Health Emergencies and Modifications to Data Standards Requirements

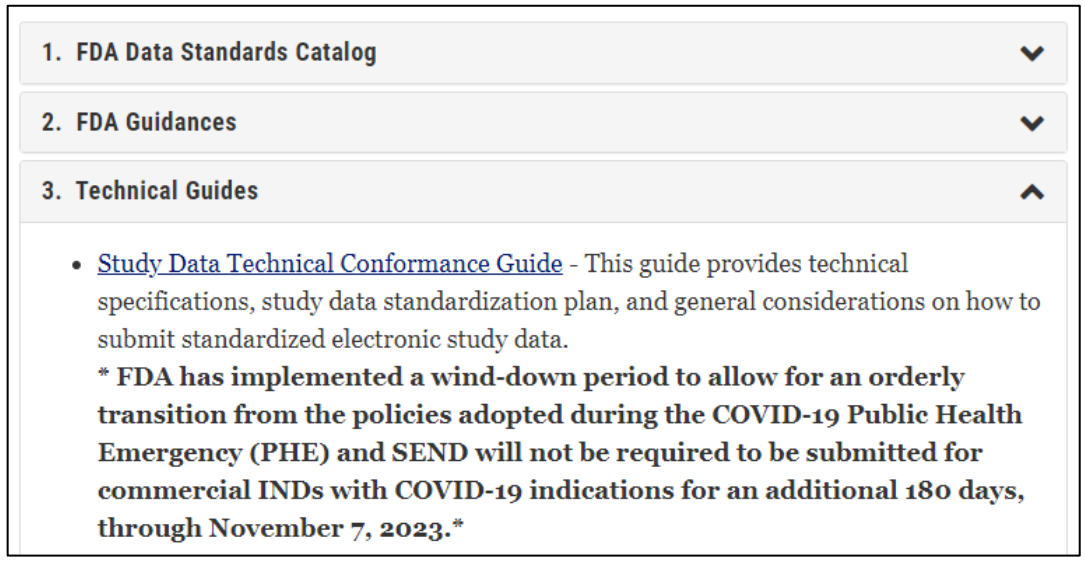
Table 7. Archive of Information About the Specific Modifications to Data Standards Requirements that Were Permitted During Specific HHS Declared Public Health Emergencies (PHEs)

Section	Details
4.1.4.7.1	**HHS Declared PHE:** SARS-CoV-2 (COVID-19) pandemic (Jan. 31, 2020 - May 11, 2023) **Impacted Electronic Data Standards:** The Standard for Exchange of Nonclinical Data (SEND) for commercial INDs submitted to CDER. **Modification to Requirement:** FDA will not require datasets in SEND format until the time of submission of a marketing application for products with COVID-19 specific indications. **Means of Public Notification:** Implementation announced in Version 4.7.1 of the Study Data TCG (June 2021) and expiration announced in Version 5.2 of the Study Data TCG (May 2023). **Rationale for Modification:** To help prevent delays in the initiation of clinical trials for products with a proposed indication to diagnose, cure, mitigate, treat, or prevent COVID-19 (COVID-19 specific indications).
	Information Published in the Study Data TCG During the PHE: HHS Declared Public Health Emergency Reference: There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[FN1]

- Addition of Appendix H to track any modifications to data standards requirements due to an HHS declared PHE.
- Lists PHE, data standards impacted, public notification and rationale.
- Maintains a history of previously used language in the Study Data TCG regarding modified data standards requirements.

Study Data TCG May 12, 2023 Update





Special Edition of the Study Data TCG published on **May 12, 2023**

Replaced language on Study Data Standards Resources Website (Technical Guides)

https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources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