

From: [Giordano, Erica](#)  
To: [Patel, Manisha \(manisha.patel@novartis.com\)](#)  
Cc: ["Riggins, Cindy"; narin.ahmed@novartis.com](#)  
Subject: BL 125646 Clinical Information Request  
Date: Friday, June 09, 2017 9:16:32 AM  
Attachments: [image005.png](#)  
[image011.png](#)  
[image012.png](#)

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Good morning,


















Please see the information request below and provide a response by 4 pm on June 16, 2017. We recommend that you contact the esub team ([esub@fda.hhs.gov](mailto:esub@fda.hhs.gov)) to determine the most efficient way to resolve this issue with the dataset.

1. The SDTM dataset for CTL019B2202 is not reviewable. The dataset currently includes multiple versions of xpt files with the same name (see below). Some of these are listed as Current, some are Amended, and some are Appended. When a data file is revised, the revision of the same name should be cumulative, and it should be submitted as a replacement for the prior version. Provide a reviewable SDTM dataset for CTL019B2202 that does not include duplicate file names.

Details	Inventory	Search	Print	Download
Inventory				
Title	File Name	Received Date	Life Cycle Status	Submitted In
m2	m2.xpt	3/2/2017	Append	0002 3/2/2017 -> 125646/0.4 (Amendment) - Recd 03/02/2017
m2	m2.xpt	2/2/2017	Amended	0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02/2017
m3	m3.xpt	3/2/2017	Append	0002 3/2/2017 -> 125646/0.4 (Amendment) - Recd 03/02/2017
m3	m3.xpt	2/2/2017	Amended	0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02/2017
mh	mh.xpt	3/2/2017	Append	0002 3/2/2017 -> 125646/0.4 (Amendment) - Recd 03/02/2017
mh	mh.xpt	2/2/2017	Amended	0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02/2017
pc	pc.xpt	2/2/2017	Current	0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02/2017
pp	pp.xpt	2/2/2017	Current	0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02/2017

2. The ADAM dataset for CTL019B2202 is not reviewable. The dataset currently includes multiple versions of xpt files with the same name (see below). Some of these are listed as Current, some are Amended, and some are Appended. When a data file is revised, the revision of the same name should be cumulative, and it should be submitted as a replacement for the prior version. Provide a reviewable ADAM dataset for CTL019B2202 that does not include duplicate file names.



Details	Inventory	Search	Print	Download
Inventory				
  				
Title	File Name	Received Date	Life Cycle Status	Submitted In
adm2	adm2.xpt	2/2/2017	 Amended	 0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02
adm3	adm3.xpt	3/2/2017	 Append	 0002 3/2/2017 -> 125646/0.4 (Amendment) - Recd 03/02/2017
adm3	adm3.xpt	2/2/2017	 Amended	 0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02
admh	admh.xpt	3/2/2017	 Append	 0002 3/2/2017 -> 125646/0.4 (Amendment) - Recd 03/02/2017
admh	admh.xpt	2/2/2017	 Amended	 0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02
adpc	adpc.xpt	2/2/2017	 Current	 0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02
adppf	adppf.xpt	2/2/2017	 Current	 0000 2/2/2017 -> 125646/0.0 (Original Application) - Recd 02/02

Please confirm receipt of this request.

Thank you,

**Erica Giordano**

Regulatory Project Manager

Center for Biologics Evaluation and Research

Office of Tissues and Advanced Therapies

U.S. Food and Drug Administration

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