

	CT28-WI-GL01- RF01 2.0	FINAL APPROVED PROTOCOL AND STATISTICAL ANALYSIS PLAN REDACTION APPROVAL FORM	31-Aug-2018
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PURPOSE: This form is to be used by the approvers of the redacted final approved protocol (FAP) and/or statistical analysis plan (SAP) for public release. FAP and SAP approver signature denotes readiness for posting to ClinicalTrials.gov. and confirms intellectual property (IP) attorney review was completed.

FAP AND/OR SAP REDACTION APPROVAL FORM

Protocol Number: A0081105

Protocol Title: A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial of Pregabalin as Adjunctive Therapy in Pediatric and Adult Subjects With Primary Generalized Tonic-Clonic Seizures - Protocol -A0081105

Amendment Number (if applicable): N/A

Version Date: 26 July 2012

Phase: 3

SAP: A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Trial of Pregabalin as Adjunctive Therapy in Pediatric and Adult Subjects With Primary Generalized Tonic-Clonic Seizures

SAP Version Date: 18 March 2019

FAP redaction approver

I have reviewed the redacted version of the FAP and confirm that it is appropriate for releasing publicly in accordance with global regulations and Pfizer policy.

☒ I confirm that IP has reviewed the redacted FAP.

Print Name:

Signature: Lynne R Pauer

068f821f-a5ed-4065-b4e3-88d6f1d5beae

Date: 26 Jul 2019
08:10:057-0400

SAP redaction approver

I have reviewed the redacted version of the SAP and confirm that it is appropriate for releasing publicly in accordance with global regulations and Pfizer policy.

PFIZER INTERNAL USE ONLY

The official version of this form is located in the electronic document management system and accessible via the eSOP portal.

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<input checked="" type="checkbox"/> I confirm that IP has reviewed the redacted SAP.	
Print Name: <i>Rana Fayyad</i>	
Signature: <i>[Signature]</i>	Date: <i>7/16/19</i>

VERSION HISTORY

Version	Effective Date	Change Type (New, Revise, Admin)	Summary of Revisions
2.0	31-Aug-2018	Admin	Administrative change - No new requirements added or process changes made. Clarified signatories and addresses minor inconsistencies with standard operating procedure (SOP) and added reminder that IP review is required according to the SOP.
1.0	15-Feb-2018	New	New form.

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