# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 216482Orig1s000

# REMS

## Appendix 1: REMS Assessment Plan

The assessment plan must include, but is not limited to, the following:

### PROGRAM OUTREACH AND COMMUNICATION

1) REMS Communication activities (provide for each reporting period and cumulatively)
   a) For both the Dear Healthcare Provider (DHCP) Letter (1&2) and the Dear Healthcare Provider (DHCP) Letter for Centers (1&2), provide the following:
      i) Sources for the distribution lists for healthcare providers
      ii) Number of healthcare providers targeted
      iii) The number of REMS materials packets sent by date and method of distribution
      iv) The number of emails successfully delivered, opened and unopened.
      v) The number of mailing successfully delivered, opened, and unopened
      vi) Date that the revised materials became available on the website
   b) For each professional society, or journal to be sent the banner provide the following:
      i) A summary of the extent to which the banner reached the intended stakeholders
      ii) The number of times the Mycophenolate REMS website was accessed via the banner

### PROGRAM IMPLEMENTATION AND OPERATIONS

2) Status of Grants (provide for each reporting period and cumulatively)
   a) The status of the request for proposals for grants for REMS-compliant accredited CE including:
      i) Date Request for Application (RFA) issued
      ii) Date and number of applications submitted in response to each RFA
      iii) RFAs awarded: date, number, and name of grantee
      iv) Date/timeframe next RFA to be issued
3) Continuing Education (CE) Program (provide each reporting period and cumulatively)
   a) For CE programs awarded during the assessment period:
      i) Description of each grantee and projected number of participants and completers

ii) For the first assessment, the date the first REMS-compliant CE based upon the FDA Mycophenolate REMS Education Blueprint became available

b) Description of Continuing Education (CE) program:

i) CE format (live, webinar, etc.)

ii) Duration of activity for live or webinar activities

iii) Average duration to complete for internet/enduring activities

iv) Education methods and tools (case-based, multimedia, didactic, interactive, adaptive, etc.)

v) A summary of all reports submitted to the Mycophenolate REMS Applications by CE grantees during the assessment period

4) Audit: The aggregate results of independent audits of the CE. Audits must include/evaluate

a) A description of the organization(s) or independent auditors (accreditation bodies of CE Providers are considered independent and eligible to conduct the audits) conducting the audit(s);

b) Whether the content of the REMS-compliant accredited CE covers all elements of the FDA Blueprint approved as part of the REMS;

c) Whether the integrated or post-course knowledge assessment measures knowledge of all section of the FDA Blueprint;

d) Whether the REMS-compliant accredited CE was conducted in accordance with the Accreditation Council for Continuing Medication Education (ACCME) standards for CE or appropriate standards for accreditation bodies

5) Healthcare Provider Training (provide for each reporting period and cumulatively)

a) The number of healthcare providers who completed the *Prescriber Training Confirmation Form* in the Shared System REMS (during the reporting period and cumulatively), stratified by prescriber specialty.

b) A summary of the methods used to complete the *Prescriber Training Confirmation Form* (i.e., online, phone, fax).

c) The number of healthcare providers who have confirmed training through the Mycophenolate REMS website and were actively prescribing mycophenolate during the reporting period (i.e., have written at least one prescription in the time period) stratified by prescriber specialty.

d) The number of healthcare providers who have completed REMS-compliant accredited CE stratified by specialty, degree, and geographic region (defined by US Census) and those who report prescribing mycophenolate.

e) Provide an analysis comparing the number of healthcare providers who

completed the *Prescriber Training Confirmation Form* and/or a REMS-compliant accredited CE program to the total number of healthcare providers prescribing a mycophenolate-containing product stratified by specialty and degree.

f) A description of any activities undertaken during the assessment reporting period to increase training, not identified in other metrics.

6) Center training (provide for each reporting period and cumulatively)
   a) The total number of centers, stratified by type of center that confirmed training (during the reporting period and cumulative).
   b) A descriptive summary of how newly confirmed centers incorporated the REMS into their center's practice (as described on the *Center Training Confirmation Form*).
   c) Total prescribers confirmed by centers.
7) Mycophenolate Utilization Data (provide for each reporting period and cumulatively)
   a) Healthcare Provider Data
      i) The number and percentage of total prescriptions dispensed, by new and refill, stratified by specialty.
      ii) The number of unique prescribers stratified by specialty.
   b) Patient Utilization Data
      i) The number of unique patients receiving mycophenolate stratified by age, gender, and reasons for use/indication.

**HEALTH OUTCOMES AND SURROGATES OF HEALTH OUTCOMES**

8) Pregnancy Exposures (provide for each reporting period and cumulatively)
   a) An analysis of the post-marketing cases of pregnancy reported in association with mycophenolate (during the reporting period and cumulative) with attention to but not limited to:
      i) The number of pregnancy exposures* reported (during the reporting period and cumulative) and stratified by source (spontaneous report, reported via the Mycophenolate REMS Call Center, enrolled in the Mycophenolate Pregnancy Registry), age, and other demographics, and if the prescriber completed the REMS training and/or reports completing REMS-compliant accredited CE training.
      ii) The duration of mycophenolate exposure data.
      iii) The pregnancy outcome for each exposed pregnancy reported (during the reporting period and cumulative).

iv) The root cause analysis of each pregnancy reported to determine the cause of the pregnancy exposure (during the reporting period and cumulative).

v) Results of any follow up from previous years' exposures.

*All pregnancy exposures reported to the applicants from any source should be reported and analyzed as part of the SSS REMS assessment plan. The cases should be linked to allow matching of the cases reported in the Mycophenolate Pregnancy Registry to cases in the global safety database.

**KNOWLEDGE**

9) Healthcare Provider Knowledge (beginning with the 3-year assessment report and each reporting period thereafter) stratified by whether the HCP reports training through the REMS website, training through the REMS-compliant accredited CE program, neither, or both.

a) An evaluation of healthcare providers' understanding of:

i) First trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy

ii) The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate

iii) The need to report pregnancies to the Mycophenolate Pregnancy Registry.

10) Patient Knowledge (beginning with the 3-year assessment report and each reporting period thereafter)

a) An evaluation of patients' understanding and awareness of the increased risks of miscarriage and birth defects when taking mycophenolate during pregnancy, and the importance of pregnancy prevention and planning when taking mycophenolate.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified.

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