

# Tracleer® REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

**NOTE: THIS FORM SHOULD NOT BE USED TOGETHER WITH THE ENROLLMENT FORM.  
USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION.**

Complete this form to:

- 1) Change the reproductive status of any female patient within 10 business days of awareness of the change in reproductive status
- 2) Complete the annual verification of the reproductive potential status for Pre-pubertal Females 8 years of age or older

Fax this form to *Actelion Pathways®* at 1-866-279-0669.

Prescriber must complete this form within 10 business days of awareness of the change in reproductive status.

## Patient Information (please print)

Patient Tracleer ID \_\_\_\_\_

First name \_\_\_\_\_ MI \_\_\_\_\_ Last name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

Birth date \_\_\_\_\_ Phone \_\_\_\_\_

## Prescriber Information (please print)

First name \_\_\_\_\_ MI \_\_\_\_\_ Last name \_\_\_\_\_

NPI # \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

Tracleer Prescriber ID (if available) \_\_\_\_\_

Office contact and email address (optional) \_\_\_\_\_

## Definitions of Reproductive Potential Status

### Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)

### Females of Non-Reproductive Potential

- Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
- Females with other medical reasons for permanent, irreversible infertility

## Select the most appropriate reason for submitting this form. (For reference, please see the Definitions of Reproductive Potential Status)

### Change in Status

- **Based on definitions of reproductive potential status, patient is (please check one):**

- Female of Reproductive Potential
- Female of Non-Reproductive Potential—Patient is pre-pubertal
- Female of Non-Reproductive Potential—Patient is post-menopausal
- Female of Non-Reproductive Potential—Other medical reasons for permanent, irreversible infertility

- **Reason for change in classification (please check one):**

- Physiological transition
- Medical/surgical (please specify): \_\_\_\_\_
- Other (please specify): \_\_\_\_\_

- **Annual Verification**

- Patient remains a Pre-Pubertal Female (8 years of age or older)

## Prescriber acknowledgement (REQUIRED)

By signing, I certify that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status.

Prescriber signature \_\_\_\_\_

Title (MD/PA/NP, etc) \_\_\_\_\_

Date \_\_\_\_\_

Please visit [www.TracleerREMS.com](http://www.TracleerREMS.com) or call 1-866-ACTELION (1-866-228-3546) for more information about the Tracleer REMS Program.

