RESEARCH SUBJECT INFORMATION SHEET

TITLE: THE SAVELLA® PREGNANCY REGISTRY

PROTOCOL NO.: MLN-MD-30
WIRB® Protocol #20091686

SPONSOR: Allergan Inc.

INVESTIGATOR: Susan Sinclair, PhD, MPH, RN
1011 Ashes Drive
Wilmington, North Carolina 28405
United States

SITE(S): INC Research
1011 Ashes Dr
Wilmington, North Carolina 28405
United States

STUDY-RELATED PHONE NUMBER(S): Registry Coordinating Center
877-643-3010 (toll-free telephone)

For women who are prescribed Savella and who become pregnant, there is little information about the health of their babies. The Savella Pregnancy Registry (listing) will help us learn more about babies whose mothers took Savella during pregnancy.

Since you have taken Savella at some point during your pregnancy, we are asking you to be a part of this registry which collects information on pregnant women such as yourself and their babies.

What do I have to do to participate?

To be a part of this registry you must be a U.S. resident and at least 18 years of age. You will not have to make any extra office visits, take any extra tests, or take any additional medications. This registry will ask you to give us some basic information about your pregnancy and your permission to contact:

- the doctor whom you are seeing during this pregnancy (for information about you and your pregnancy) and
- your baby's doctor after the delivery (to collect information about your baby)

You may give the registry your information and your permission to participate over the phone. With your permission, we will request information directly from your doctor and your baby's doctor about your condition, your general well-being during pregnancy, and the well-being of your baby at birth, 4 months, and 12 months of age.

What kind of information will be given to the registry?

The registry will need information about you and your pregnancy. We will ask you about your use of Savella and any other drugs you are taking during pregnancy. Your doctor will be asked to provide information about the history of any previous pregnancies, their outcome(s), and information about any risks related to your pregnancy.

Information about you will be collected at enrollment, at the end of the second trimester, (around week 28 of your pregnancy), after your delivery, and when your infant is 4 months and 12 months old. You have the right to know what information is being processed and have the right to correct it as needed.

Risks and Discomforts

The registry uses a series of questionnaires to gather information and does not involve any medical procedures. For these reasons, the only risks or discomforts that are expected are related to the possible loss of confidentiality and/or the emotional discomfort answering some of the questions.

Benefits

There may be benefits to other participants like you in the future. The results of this registry may increase medical knowledge about the safety of using Savella during pregnancy.

Expenses

You will not have any additional expenses as a result of your participation in this registry.

Payment for Participation

You will not be paid for taking part in this study.

Alternatives

Your alternative is to not be in this study.

Source of Funding

Funding for this research study will be provided by Allergan.

What if I decide not to participate?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

You may withdraw from the registry at any time. If you choose to be a part of the registry, and decide later that you want to stop allowing information to be given to the registry, you may let us know by sending a letter to the registry at the address at the top of this information sheet or you may contact us directly at 1-877-643-3010. We will be allowed to use data collected before withdrawal of your consent. If you decide not to participate or to stop participating later, your and your baby's medical care will not be affected.

Your participation in this registry may be stopped at any time at the discretion of your doctor and the sponsor company without your consent for any reason.

New Information

If any increased risk of harm is recognized during the registry, you will be informed and specific information may be requested from you for further evaluation.

Questions

If at any time you have questions, concerns or complaints regarding this registry, you may contact the Registry Coordinating Center at 1-877-643-3010 or you may let us know by sending a letter to the registry at the address at the top of this consent form.

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE #120
Puyallup, Washington 98374
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a copy of this consent form.

Informed Consent

I have read the information in this consent form (or it has been read to me). The registry representative, whose signature is given below, has informed me about the nature of The Savella Pregnancy Registry. I have had enough opportunity to ask questions. All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

By giving information sheet, I have not given up any of my legal rights.

☐ Verbal consent given by subject to the registry representative over the phone:

_____
Date

_____ _____
Signature of Person Conducting Informed Consent Discussion (Registry Representative) Date

_____ _____
Printed Name of Subject Date of Birth

_____ _____
Signature of Subject (optional) Date

☐ Subject declined providing two additional contacts

Additional Contacts for Subject listed above (must reside at a different address):

_____
Printed Name of Additional Contact #1

_____
Address of Additional Contact #1

_____
Phone number of Additional Contact #1

Printed Name of Additional Contact #2

Address of Additional Contact #2

Phone number of Additional Contact #2

REQUEST FOR RELEASE OF MEDICAL INFORMATION

I HEREBY REQUEST THAT MEDICAL INFORMATION AND/OR MEDICAL RECORDS RELATED TO MY PREGNANCY BE RELEASED TO:

The Savella® Pregnancy Registry Coordinating Center
INC Research/inVentiv Health
1011 Ashes Drive Wilmington,
NC 28405
Phone number: 1-877-643-3010
Fax number: 1-800-800-1052

RECORDS TO BE RELEASED FROM:

Name of Health Care Provider: _____

Name of Practice: _____

HCP Specialty: ☐ Obstetric HCP ☐ Other: _____ (please specify)

Address: _____

_____

Telephone number: _____ Fax number (if available): _____

Email (if available): _____

Comments: _____

_____

Patient's Date of Birth: _____

☐ Verbal consent given by Patient to Registry Representative over the phone on: _____ Date

_____ _____
Signature of Registry Representative Date

_____
Printed Name of Patient

_____ _____
Signature of Patient (optional) Date

Address of Patient: _____

_____

Telephone Number of Patient: _____

Email of Patient (if available): _____

REQUEST FOR RELEASE OF MEDICAL INFORMATION

I HEREBY REQUEST THAT MEDICAL INFORMATION AND/OR MEDICAL RECORDS RELATED TO MY INFANT BE RELEASED TO:

The Savella® Pregnancy Registry Coordinating Center
INC Research/inVentiv Health
1011 Ashes Drive
Wilmington, NC 28405
Phone number: 1-877-643-3010
Fax number: 1-800-800-1052

RECORDS TO BE RELEASED FROM:

Name of Health Care Provider: _____

Name of Practice: _____

HCP Specialty: ☐ Pediatric HCP ☐ Other: _____ (please specify)

Address: _____

_____

Telephone number: _____ Fax number (if available): _____

Email (if available): _____

Comments: _____

Infant's Date of Birth: _____ Infant's Gender: ☐ Male ☐ Female

☐ Verbal consent given by Patient to Registry Representative over the phone on: _____ Date

_____
Signature of Registry Representative Date

_____
Printed Name of Infant

_____
Printed Name of Infant's Mother

_____
Signature of Infant's Mother (optional) Date

Address of Infant's Mother: _____

_____

Telephone Number of Infant's Mother: _____

Email of Infant's Mother (if available): _____

HOJA DE INFORMACIÓN DEL SUJETO DE UNA INVESTIGACIÓN

TÍTULO: REGISTRO DE EMBARAZOS CON SAVELLA.

N.º DE PROTOCOLO: MLN-MD-30
N.º de protocolo del WIRB® 20091686

PATROCINADOR: Forest Laboratories, Inc.
Jersey City, New Jersey
Estados Unidos

INVESTIGADOR: Jessica Albano, Ph.D.
1011 Ashes Drive
Wilmington, North Carolina 28405
Estados Unidos

INSTITUCIÓN: Kendle International Inc.
1011 Ashes Drive
Wilmington, North Carolina 28405
Estados Unidos

NÚMERO DE TELÉFONO DEL ESTUDIO: Centro de Coordinación del Registro
877-643-3010 (teléfono gratuito)

Para las mujeres a las que se les receta Savella y que se embarazan, hay poca información sobre la salud de sus bebes. El Registro de Embarazos con Savella (lista) nos ayudará a aprender más sobre los bebés cuyas madres tomaron Savella durante el embarazo.

Dado que usted tomó Savella en algún momento durante el embarazo, le pedimos que participe en este registro, en el cual se reúne información sobre mujeres embarazadas, como usted, y sobre sus bebés.

¿Qué debo hacer para participar?

Para participar en este registro debe ser residente de los EE. UU. y tener por lo menos 18 años de edad. No tendrá que hacer más visitas al consultorio, realizarse más análisis ni tomar más medicamentos. Para este registro le pediremos cierta información básica sobre su embarazo y su permiso para comunicarnos con:

- El médico que verá durante este embarazo (para obtener información sobre usted y su embarazo).
- El médico del bebé después del parto (para reunir información sobre su bebé).

La información y el permiso para participar los puede dar por teléfono al registro. Con su permiso, solicitaremos información directamente al médico que la atiende a usted y a su bebé sobre su estado de salud, su bienestar general durante el embarazo y el bienestar de su bebé al nacer, a los 4 meses y a los 12 meses de edad.

¿Qué tipo de información se dará al registro?

El registro necesitará información sobre usted y sobre su embarazo. Le preguntaremos sobre el uso de Savella y otros fármacos que tome durante el embarazo. Se le pedirá al médico que la atiende que dé información sobre antecedentes de embarazos anteriores, el desenlace e información sobre algún riesgo relacionado con su embarazo.

Se reunirá información sobre usted en el momento de la inscripción, al final del segundo trimestre (alrededor de la semana 28 de su embarazo), después del parto y cuando su hijo tenga 4 y 12 meses de edad. Tiene derecho de saber qué información se está procesando y de hacerle las correcciones necesarias.

Riesgos y molestias

El registro utiliza una serie de cuestionarios para reunir información y no implica ningún procedimiento médico. Por estos motivos, los únicos riesgos o molestias que se esperan están relacionados con la posible pérdida de la confidencialidad y/o molestias emocionales al contestar algunas preguntas.

Beneficios

Es posible que se generen algunos beneficios para otras participantes como usted en el futuro. Los resultados de este registro pueden aumentar el conocimiento médico sobre la seguridad de utilizar Savella durante el embarazo.

Gastos

No tendrá gastos adicionales como resultado de su participación en este registro.

Pago por la participación

Usted no recibirá ningún pago por participar en este estudio.

Alternativas

La alternativa que tiene es no participar en este estudio.

Origen del financiamiento

Los fondos necesarios para este estudio de investigación serán proporcionados por Forest Laboratories, Inc.

¿Qué sucede si decido no participar?

Su participación en este estudio es voluntaria. Puede decidir no participar o puede retirarse del estudio en cualquier momento. Su decisión no tendrá como resultado ningún castigo ni la pérdida de los beneficios que le corresponden.

Usted puede retirarse del registro en cualquier momento. Si elige participar en el registro y más adelante decide que ya no quiere permitir que se proporcione información al registro, puede comunicárnoslo enviando una carta al registro a la dirección que aparece al inicio de esta hoja de información o puede comunicarse con nosotros directamente al 1-877-643-3010. Podremos utilizar los datos reunidos antes de que haya retirado su consentimiento. Si decide no participar o dejar de participar más adelante, no se verá afectada la atención médica que usted o su bebé reciban.

El médico y la compañía del patrocinador pueden detener su participación en este registro según su criterio, en cualquier momento, sin su consentimiento, por cualquier motivo.

Información nueva

Si se reconoce que el riesgo de sufrir un daño durante el registro ha aumentado, se le comunicará y es posible que se solicite información específica para su evaluación posterior.

Preguntas

Si en algún momento tiene preguntas, preocupaciones o quejas relacionadas con este registro, puede comunicarse con el Centro de Coordinación del Registro al 1-877-643-3010 o puede comunicárnoslo enviando una carta al registro, a la dirección que aparece en la parte superior de este formulario de consentimiento.

Si tiene preguntas sobre sus derechos como sujeto de una investigación o si tiene preguntas, preocupaciones o quejas sobre la investigación, puede comunicarse con:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Teléfono: 1-800-562-4789 ó 360-252-2500
Correo electrónico: Help@wirb.com

El WIRB es un grupo de personas que realizan revisiones de las investigaciones de manera independiente.

El WIRB no podrá responder preguntas específicas del estudio, como preguntas sobre los horarios de las citas. Sin embargo, puede comunicarse con el WIRB si no puede localizar al personal de la investigación o si quiere hablar con alguien que no sea parte del personal.

No firme este formulario de consentimiento a menos que haya podido hacer preguntas y haya recibido respuestas satisfactorias a todas ellas.

Si acepta participar en este estudio, recibirá una copia de este formulario de consentimiento.

Consentimiento informado

He leído (o me han leído) la información de este formulario de consentimiento. El representante del registro, cuya firma aparece abajo, me ha informado sobre la naturaleza del Registro de Embarazos con Savella. He tenido suficiente oportunidad de hacer preguntas. Todas mis preguntas sobre el estudio y sobre mi participación en él han sido respondidas. Doy mi consentimiento libremente para participar en este estudio de investigación.

Al entregar la hoja de información, no renuncio a ninguno de mis derechos legales.

☐ Consentimiento verbal otorgado por el sujeto al representante del registro por teléfono:

_____
Fecha

_____ _____
Firma de la persona a cargo del análisis del consentimiento informado (representante del registro) Fecha

_____ _____
Nombre de la participante (en letra de imprenta) Fecha de nacimiento

_____
Dirección de la participante

_____

_____ _____
Firma de la participante (opcional) Fecha

wirb/forest laboratories/20091686/trans. 10/20/2009/nwt/vbo

SOLICITUD PARA ENTREGAR INFORMACIÓN MÉDICA

POR LA PRESENTE SOLICITO QUE LA INFORMACIÓN MÉDICA Y/O HISTORIA CLÍNICA RELACIONADA CON MI EMBARAZO SE ENTREGUE A:

Centro de Coordinación del Registro de Embarazos con Savella™
Kendle International Inc. (Kendle)
Research Park, 1011 Ashes Drive
Wilmington, NC 28405
Número de teléfono: 1-877-643-3010
Número de fax: 1-800-800-1052

DATOS DE LA PERSONA QUE ENTREGARÁ LOS REGISTROS:

Nombre del proveedor de atención médica: _____

Nombre del consultorio: _____

Especialidad del HCP: ☐ HCP de obstetricia ☐ Otro: _____
(Especifique)

Dirección: _____

_____

Número de teléfono: _____ Número de fax (si está disponible): _____

Correo electrónico (si está disponible): _____

Comentarios: _____

_____

Fecha de nacimiento de la paciente: _____

☐ Consentimiento verbal otorgado por
la paciente al representante del registro por teléfono el día: _____
Fecha

_____
Firma del representante del registro Fecha

_____
Nombre de la paciente (en letra de imprenta)

_____
Firma de la paciente (opcional) Fecha

Dirección de la paciente: _____

_____

Número de teléfono de la paciente: _____

Correo electrónico de la paciente (si está disponible): _____

SOLICITUD PARA ENTREGAR INFORMACIÓN MÉDICA

POR LA PRESENTE SOLICITO QUE LA INFORMACIÓN MÉDICA Y/O HISTORIA CLÍNICA RELACIONADA CON MI BEBÉ SE ENTREGUE A:

Centro de Coordinación del Registro de Embarazos con Savella™
Kendle International Inc. (Kendle)
Research Park, 1011 Ashes Drive
Wilmington, NC 28405
Número de teléfono: 1-877-643-3010
Número de fax: 1-800-800-1052

DATOS DE LA PERSONA QUE ENTREGARÁ LOS REGISTROS:

Nombre del proveedor de atención médica: _____

Nombre del consultorio: _____

Especialidad del HCP: ☐ HCP de pediatría ☐ Otro: _____
(Especifique)

Dirección: _____

_____

Número de teléfono: _____ Número de fax (si está disponible): _____

Correo electrónico (si está disponible): _____

Comentarios: _____

Fecha de nacimiento del bebé: _____ Sexo del bebé: ☐ Masculino ☐ Femenino

☐ Consentimiento verbal otorgado por
la paciente al representante del registro por teléfono el día: _____
Fecha

_____
Firma del representante del registro Fecha

_____
Nombre del bebé (en letra de imprenta)

_____
Nombre de la madre del bebé (en letra de imprenta)

_____
Firma de la madre del bebé (opcional) Fecha

Dirección de la madre del bebé: _____

_____

Número de teléfono de la madre del bebé: _____

Correo electrónico de la madre del bebé (si está disponible): _____

CRF Definitions/Completion Instructions for the **Registration Form**
The Savella® Pregnancy Registry
US Phone: 1-877-643-3010; US Fax: 1-800-800-1052

Please DO NOT Send MEDICAL RECORDS

DEFINITIONS

Case Report Form (CRF)	Document designed to record all of the required information to be reported to Forest on each registry participant. To be completed by the pregnant patient's health care provider or by the Registry Associate receiving the information via telephone contact with the pregnant patient or with the health care provider.

GENERAL INSTRUCTIONS

All Fields – do not leave blank	Line through or write "UNK" if unknown. Fields on the CRFs left blank will prompt a phone call to the health care provider for data clarification.
Dates	All dates should be in **dd mmm yyyy** format (e.g., January 1, 2009 is written 01-Jan-2009).

Instructions for the REGISTRY COORDINATING CENTER

For Office Use Only	The Registry Coordinating Center will complete this section.
Registry ID	Provide the Registry assigned, non-identifying patient ID number on all pages of the case report form.
Registry date of notification	If the registration information was obtained by phone, the date of notification should be the date the Registry first received the call & the box for phone should be checked. If the registration information was obtained as a paper CRF enter the date the HCP signed the forms. If no signature and/or date is present, enter the date the Registry received the information. If initial reporter was sponsor the earliest date available should be used.
Phone	If the form was completed by the ICRA over the phone, check the "Phone" box.

SECTION 1

Inclusion Criteria	**Patient must meet one requirement from each of 1.1 – 1.6 in order to be eligible for participation.** There should be a total of six boxes checked in order to be eligible.

SECTION 2

Maternal Information	**2.1 Last Menstrual Period (LMP):** Provide the date of the pregnant patient's last menstrual period, or indicate that the LMP is unknown by placing a check in the "unknown" box. If the patient is unable to provide the exact date, record the best estimate of the date. **2.2 Estimated Date of Delivery (EDD)** *(by LMP):* If available, provide the estimated date of delivery, determined by the LMP, or indicate that the EDD is unknown by placing a check in the "unknown" box. **2.3 Corrected Estimated Date of Delivery (CEDD):** If available, provide the CEDD which is based on a prenatal test (e.g., ultrasound). This is especially important if this is the date being used to calculate gestational ages for medication exposures and outcome. If the CEDD is unknown place a check in the "unknown" box. **2.4** Indicate whether the patient has enrolled in this registry for a previous pregnancy by checking the "yes" or "no" box.

	2.5 Height: Provide in feet and inches (e.g. 5 feet 02 inches). **2.6 Pre-Pregnancy Weight:** Please provide the patient's pre-pregnancy weight in pounds (e.g. 125.5 lbs). **2.7 Patient's Age at Conception:** Please provide the patient's age, in years, at time of conception. **2.8 Ethnicity:** Indicate whether the patient is Hispanic or Latino by checking the "yes" or "no" box. **2.9 Race:** Please check one appropriate box for the pregnant patient's race. If the patient is of mixed race check "Other (Specify)" and specify in the blank space the mixed race.

SECTION 3

Maternal Obstetrical History	• **# of previous pregnancies:** Indicate the number of previous pregnancies (excluding the current pregnancy). • **# of previous full-term live births:** Indicate the number of previous full-term live births this patient has experienced. • **# of previous preterm live births:** Indicate the number of previous preterm live births this patient has experienced. • **# of previous spontaneous abortions:** Indicate the number of previous spontaneous abortions or miscarriages this patient has experienced. • **# of previous outcomes with birth defects:** Indicate the number of previous pregnancies with birth defects the patient has experienced. This number is independent of the pregnancy outcome (e.g. live birth, stillbirth, etc.). **Specify the details of any previous pregnancies with birth defects identified above.** • **# of previous elective abortions:** Indicate the number of previous elective abortions or terminations the patient has experienced. • **# of previous ectopic pregnancies:** Indicate the number of previous ectopic pregnancies the patient has experienced. • **# of previous molar pregnancies:** Indicate the number of previous molar pregnancies the patient has experienced. • **# of previous stillbirths:** Indicate the number of previous stillbirths the patient has experienced. **List any complications the patient experienced during previous pregnancies.**

SECTION 4

Personal or Family History of Birth Defects:	Check "none" if the patient does not have a personal or family history of birth defects. If history is unknown check the "UNK" box. If birth defects are known, please provide the birth defect under the appropriate family member's relationship to the patient in the spaces provided.

Health Care Provider	The health care provider is to sign and print his/her name, as well as date, and provide his/her title. If the health care provider is not the reporter, please indicate the name and title of the person completing the form.

THE SAVELLA® PREGNANCY REGISTRY

REGISTRATION FORM

Return by FAX to: 800-800-1052
Registry Phone Number: 877-643-3010
1011 Ashes Drive Wilmington, NC 28405

FOR OFFICE USE ONLY

☐ Update

Registry ID _____

Registry date of notification _____ _____ _____ (dd mmm yyyy)

☐ Phone

MOTHER'S NAME: _____ **MOTHER'S DATE OF BIRTH:** _____ _____ _____ (dd mmm yyyy)

1. INCLUSION CRITERIA *(Patient must meet one requirement from each of 1.1 – 1.6 in order to be eligible for participation)*

1.1 ☐ Exposure to Savella® at any time during pregnancy, beginning on or after the first day of the last menstrual period (LMP).

1.2 ☐ Patient is currently pregnant - OR -

☐ Patient is not currently pregnant; a birth defect was noted at outcome and the outcome occurred within 2 years of initial report.

1.3 ☐ Patient has provided consent to participate in this registry and on behalf of her child.

1.4 ☐ Patient agrees to provide consent for release of obstetrical and pediatric medical information.

1.5 ☐ Patient is a U.S. resident.

1.6 ☐ Patient is at least 18 years of age.

2. MATERNAL INFORMATION

2.1 Last Menstrual Period (LMP): _____ _____ _____ (dd mmm yyyy)
☐ Unknown

2.2 Estimated Date of Delivery (EDD): _____ _____ _____ (dd mmm yyyy)
(by LMP)
☐ Unknown

2.3 Corrected Estimated Date of Delivery (CEDD): _____ _____ _____ (dd mmm yyyy)
(e.g. by ultrasound)
☐ Unknown

2.4 Did the patient enroll in this Registry for a previous pregnancy? ☐ Yes ☐ No

2.5 Height: _____ feet _____ _____ inches

2.6 Pre-Pregnancy Weight: ___ ___ ___ . ____ lbs.

2.7 Patient's Age at Conception _____ Years

2.8 Ethnicity: Hispanic or Latino? ☐ Yes ☐ No

2.9 Race:
☐ White/Caucasian
☐ Black/African American
☐ American Indian/Alaska Native
☐ Asian
☐ Native Hawaiian/Other Pacific Islander
☐ Other (Specify _____)

3. MATERNAL OBSTETRICAL HISTORY

of previous pregnancies: ***(excluding current pregnancy)*** _____

# of previous full-term live births: _____

# of previous preterm live births: _____

# of previous spontaneous abortions: _____

# of previous outcomes with birth defects: _____

Please specify defect(s): _____

_____

# of previous elective abortions: _____

# of previous ectopic pregnancies: _____

# of previous molar pregnancies: _____

# of previous stillbirths: _____

Please describe previous pregnancy complications : _____

_____

_____

4. PERSONAL AND FAMILY HISTORY OF BIRTH DEFECTS: ☐ NONE ☐ UNKNOWN

Maternal Birth Defect(s)	Paternal Birth Defect(s)	Family History of Birth Defect(s)
1. _____	1. _____	1. _____
2. _____	2. _____	2. _____
3. _____	3. _____	3. _____

Provider's Signature _____ Date ____ _____ _____ (dd mmm yyyy)

Provider's Printed Name _____

Name of Reporter Completing Form If Other Than Provider _____ Title _____

CRF Definitions/Completion Instructions for the **Prenatal Tests, Medications, and Concurrent Conditions Form**

The Savella® Pregnancy Registry

US Phone: 1-877-643-3010; US Fax: 1-800-800-1052

Please DO NOT Send MEDICAL RECORDS

DEFINITIONS

Case Report Form (CRF)	Document designed to record all of the required information to be reported to Forest on each registry participant. To be completed by the pregnant patient's health care provider or by the Registry Associate receiving the information via telephone contact with the pregnant patient or with the health care provider.

GENERAL INSTRUCTIONS

All Fields – do not leave blank	Line through or write "UNK" if unknown. Fields on the CRFs left blank will prompt a phone call to the health care provider for data clarification.
Dates	All dates should be in **dd mmm yyyy** format (e.g., January 1, 2009 is written 01-Jan-2009).

Instructions for the REGISTRY COORDINATING CENTER

For Office Use Only	The Registry Coordinating Center will complete this section.
Registry ID	Provide the Registry assigned, non-identifying patient ID number on all pages of the case report form.
Registry date of notification	This date should correspond with the registry date of notification on the Registration form. If the registration information was obtained by phone, the date of notification should be the date the Registry first received the call & the box for "phone" should be checked. If the registration information was obtained as a paper CRF enter the date the HCP signed the forms. If no signature and/or date is present, enter the date the Registry received the information. If initial reporter was sponsor, the earliest date available should be used.
2nd Trimester date received	This is the date that the 2nd trimester information was received; occurs at the end of the 2nd trimester. If the information was obtained by phone, the box for "phone" should be checked next to date received.
Outcome date received	This is the date that pregnancy outcome information was received. If the information was obtained by phone the box for "phone" should be checked next to date received.

SECTION 1

Prenatal Imaging and Aneuploidy Screening/Testing	• Indicate whether a prenatal test was performed by marking "yes" or "no." If unknown whether prenatal tests were performed, mark "unknown." • **Prenatal Test Name:** Provide the name of the prenatal test (e.g., ultrasound, amniocentesis, CVS). • **Prenatal Test Date:** Please provide the date the prenatal test was performed. • **Indication for Test:** for screening, write "1" if the reason is not screening, mark "2" for "other" and specify the indication for the test. • **Was a fetal abnormality noted:** If a fetal abnormality has been noted on a prenatal test, write "1" for "yes." If there have been no fetal abnormalities noted, write "2" for "no." **If a fetal abnormality was noted on a prenatal test, please describe.**

CRF Definitions/Completion Instructions for the **Prenatal Tests, Medications, and Concurrent Conditions Form**
The Savella® Pregnancy Registry
US Phone: 1-877-643-3010; US Fax: 1-800-800-1052

SECTION 2

Savella Exposure Information	**2.1 Indication:** Please check either "Fibromyalgia" or "Other (specify)" and specify other indication. • **Total Daily Dose:** Please provide the total daily dose in milligrams. • **Date OR Gestation Week Course Began**: Please provide the date or gestation week the patient began taking Savella. If exposure occurred prior to conception, a "0" may be written. • **Date OR Gestation Week Course Stopped**: Please provide the date or gestation week the patient stopped taking Savella. Check the "ongoing" box if the exposure is ongoing throughout this pregnancy.

SECTION 3

Other Drug Exposure During This Pregnancy	• If the patient has had any other drug exposures during this pregnancy please mark "yes" and list the medication(s). If the patient has not had any other drug exposures during this pregnancy, please mark "no." If exposure history is unknown, mark "unknown." • **Name of Medication or Exposure**: Provide the name of the medication or exposure (e.g. levothyroxine). • **Indication**: Provide the indication for the medication or exposure (e.g. hypothyroidism). • **Dose**: Provide the dose (e.g. 25, 50, 75). • **Units**: Provide the units (e.g. mg, mcg). • **Frequency**: Provide the frequency for the medication (e.g. daily, BID, weekly). • **Route**: Provide the route of the medication (e.g. oral, sub-q, IM). • **Date OR Gestation Week Exposure Began**: Indicate the date or the gestation week the medication exposure started. If exposure occurred prior to conception, a "0" may be written. • **Date OR Gestation Week Exposure Stopped**: Indicate the date or the gestation week the medication exposure stopped. Check the "ongoing" box if the exposure is ongoing throughout this pregnancy.

SECTION 4

Tobacco, Alcohol, and Recreational Drug Use	• Please indicate alcohol, tobacco, recreational drug use by checking appropriate boxes. If there is no history of use during this pregnancy, mark "no." If any are unknown, check the "unknown" box next to each. Please specify the type of recreational drug, if applicable. • Appropriate boxes should be checked if exposure(s) noted prior to conception and/or throughout pregnancy.

SECTION 5

Concurrent Medical Conditions During This Pregnancy &/or Maternal Complications	• **Concurrent Medical Conditions**: If the patient does not have any concurrent medical conditions, mark "none." If medical conditions are unknown, mark "unknown." • If the patient has a concurrent medical condition, name the condition (e.g. chronic hypertension, pre-eclampsia, gestational diabetes) and mark whether it is, or is not, associated with this pregnancy or

	whether it's unknown if associated with this pregnancy. • **Date OR Gestation Week Condition Started:** Indicate the date or gestation week the concurrent medical condition began. If the condition began prior to conception, a "0" may be written. • **Date OR Gestation Week Condition Stopped:** Indicate the date or gestation week the concurrent medical condition stopped. Check the "ongoing" box if the condition was ongoing throughout this pregnancy.

Health Care Provider	The health care provider is to sign and print his/her name, as well as date, and provide his/her title. If the health care provider is not the reporter, please indicate the name and title of the person completing the form.

THE SAVELLA® PREGNANCY REGISTRY

PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS FORM

(Initiated at registration and updated at each follow-up)

Return by FAX to: 800-800-1052
Registry Phone Number: 877-643-3010
1011 Ashes Drive Wilmington, NC 28405

FOR OFFICE USE ONLY

☐ Update

Registry ID _____

Registry date of notification _____ _____ _____ (dd mmm yyyy) ☐ Phone

2nd Trimester date received _____ _____ _____ (dd mmm yyyy) ☐ Phone

Outcome date received _____ _____ _____ (dd mmm yyyy) ☐ Phone

1. PRENATAL IMAGING AND ANEUPLOIDY SCREENING / TESTING *(e.g., ultrasound, amniocentesis, MSAFP, CVS)*

Was a prenatal test performed? ☐ Yes ☐ No ☐ Unknown

Prenatal Test Name	Test Date (dd/mmm/yyyy)	Indication for Test 1=Screening 2=Other, Specify	Was a fetal abnormality noted? 1 = Yes 2 = No	If a fetal abnormality was noted, please describe *(Please list only one fetal abnormality per line)*
1.				
2.				
3.				
4.				
5.				
6.				
7.				

2. SAVELLA EXPOSURE INFORMATION DURING THIS PREGNANCY

2.1 Indication: ☐ Fibromyalgia ☐ Other:_____ (specify)

Course #	Name	Total Daily Dose (mg)	Date OR Gestation Week Course Began *(dd/mmm/yyyy) (0=prior to conception)*	Date OR Gestation Week Course Stopped *(dd/mmm/yyyy) or (✓) if ongoing*
1.	Savella			☐ Ongoing
2.	Savella			☐ Ongoing
3.	Savella			☐ Ongoing
4.	Savella			☐ Ongoing
5.	Savella			☐ Ongoing
6.	Savella			☐ Ongoing

THE SAVELLA® PREGNANCY REGISTRY

PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS FORM

Return by FAX to: 800-800-1052
Registry Phone Number: 877-643-3010
1011 Ashes Drive Wilmington, NC 28405

FOR OFFICE USE ONLY

☐ Update

Registry ID _____

3. OTHER DRUG EXPOSURE DURING THIS PREGNANCY

Has the patient had other drug exposures during this pregnancy? (e.g. prescription, non-prescription or "over-the-counter", herbal supplement, vaccination, etc.)
☐ Yes ☐ No ☐ Unknown

Name of Medication or Exposure	Indication	Dose	Units	Frequency	Route	Date OR Gestation Week Began *(dd/mmm/yyyy) (0=prior to conception)*	Date OR Gestation Week Stopped *(dd/mmm/yyyy) or (✓) if ongoing*
1.							☐ Ongoing
2.							☐ Ongoing
3.							☐ Ongoing
4.							☐ Ongoing
5.							☐ Ongoing
6.							☐ Ongoing
7.							☐ Ongoing
8.							☐ Ongoing
9.							☐ Ongoing
10.							☐ Ongoing

4. TOBACCO, ALCOHOL AND RECREATIONAL DRUG USE

	Prior to Conception (✓)	1st Trimester (✓)	2nd Trimester (✓)	3rd Trimester (✓)	(✓) if Ongoing
1. Alcohol ☐ Yes ☐ No ☐ Unknown					
2. Tobacco ☐ Yes ☐ No ☐ Unknown					
3. Recreational Drug Use ☐ Yes ☐ No ☐ Unknown If yes, specify _____					

THE SAVELLA® PREGNANCY REGISTRY

PRENATAL TESTS, MEDICATIONS, AND CONCURRENT CONDITIONS FORM

Return by FAX to: 800-800-1052
Registry Phone Number: 877-643-3010
1011 Ashes Drive Wilmington, NC 28405

FOR OFFICE USE ONLY

☐ Update

Registry ID _____

5. CONCURRENT MEDICAL CONDITIONS DURING THIS PREGNANCY &/OR MATERNAL COMPLICATIONS

(e.g. chronic hypertension, pre-eclampsia, eclampsia, gestational hypertension, pre-gestational or gestational diabetes, epilepsy, thyroid disorder)

CONCURRENT MEDICAL CONDITIONS ☐ None ☐ Unknown	**Date OR Gestation Week Condition Started** *(dd/mmm/yyyy)* 0=prior to conception	**Date OR Gestation Week Condition Stopped** *(dd/mmm/yyyy)* or (✓) if ongoing
1. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
2. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
3. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
4. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
5. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
6. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
7. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
8. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
9. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
10. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing
11. ☐ Associated with Pregnancy ☐ Unknown ☐ Not Associated with Pregnancy		☐ Ongoing

Provider's Signature _____ Date ____ _____ _____
dd mmm yyyy

Provider's Printed Name _____

Name of Reporter Completing Form If Other Than Provider _____ Title _____