

<https://www.fda.gov/science-research/womens-health-research/list-pregnancy-exposure-registries>

最終確認日：2022年3月28日

Pregnancy exposure registries are studies that collect health information on exposure to medical products such as drugs and vaccines during pregnancy. FDA does not conduct any pregnancy registries. The registries on this page are posted based on a sponsor or investigator's request to list their registry. FDA does not endorse any registry and is not responsible for the content of registries listed on this webpage. This webpage may not represent a comprehensive list of pregnancy exposure registries. If you would like your registry added to this list, please email FDA at Registries@fda.hhs.gov. This webpage is intended for informational purposes only.

(1) COVID-19 Vaccines

【デジタルヘルス企業】

COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER)

<https://c-viper.pregistry.com/>

Pregistry is a proud member of StartUp Health. StartUp Health is a global entrepreneurship development company for Healthcare Transformers™. StartUp Health has the world's largest portfolio of digital health companies and offers entrepreneurs The StartUp Health Academy and The StartUp Health Network. Pregistry is a United States-based company that conducts epidemiological studies on a variety of topics, including the safety of COVID-19 vaccines and therapeutics on pregnant women and their offspring.

(2) REYVOW (lasmiditan)

【製薬企業】

Migraine Pregnancy Registry (Lilly) . . . coming soon

<https://migrainepregnancyregistry.com/>

(3) Abilify (aripiprazole)

【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School



<https://womensmentalhealth.org/research/pregnancyregistry/>

- ① National Pregnancy Registry for Atypical Antipsychotics
<https://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/>
- ② National Pregnancy Registry for Antidepressants (NPRAD)
<https://womensmentalhealth.org/research/pregnancyregistry/antidepressants/>
- ③ National Pregnancy Registry for ADHD
<https://womensmentalhealth.org/research/pregnancyregistry/adhd-medications/>
- ④ National Pregnancy Registry for Sedative Hypnotics and Other Sleep Medications
<https://womensmentalhealth.org/research/pregnancyregistry/sleep-medications/>

The National Pregnancy Registry for Psychiatric Medications is dedicated to evaluating the safety of psychiatric medications such as antidepressants, ADHD medications, and atypical antipsychotics that many people take during pregnancy to treat a wide range of mood, anxiety, executive function, or psychiatric disorders. The goal of this Registry is to gather information on the safety of these medications during pregnancy, as current data is limited.

If you are pregnant and have taken an antidepressant, ADHD medication, or atypical antipsychotic, please click the participation information button above. Individuals with a history of psychiatric illness who are pregnant and have not taken an antidepressant, ADHD medication, or atypical antipsychotic are also welcome to enroll in the Registry.

National Pregnancy Registry for Psychiatric Medications は、抗うつ薬、ADHD 薬、および

Current Sponsors:

Alkermes, Inc. (2016-Present); Aurobindo Pharma (2020-Present); Johnson & Johnson/Janssen Pharmaceuticals, Inc (2019-Present); Otsuka America Pharmaceutical, Inc.

(2008-Present); Sage Therapeutics (2019-Present); Sunovion Pharmaceuticals, Inc. (2011-Present); Supernus Pharmaceuticals (2021-Present); Teva Pharmaceutical Industries Ltd. (2018-Present).

Past Sponsors:

Forest/Actavis/Allergan (2016-2018, declined to sponsor: 2018-Present), AstraZeneca Pharmaceuticals (2009-2014, declined to sponsor: 2014-Present); AuroMedics Pharma LLC (2021-2022, declined to sponsor: 2022-Present); Ortho-McNeil-Janssen Pharmaceuticals, Inc (2009-2014, declined to sponsor: 2015-Present); Pfizer, Inc. (2009-2011, declined to sponsor: 2012-Present).

Declined to sponsor:

Apotex Inc.; Eli Lilly and Company; Novartis Pharmaceuticals; Vanda Pharmaceuticals Inc. Funding Information: Manufacturers of psychiatric medications have been approached regarding funding of the National Pregnancy Registry. Regardless of which entities have supported this initiative, all medications in this class are studied. For more information on how to sponsor the Registry, please see the contact information below.

RECENT PUBLICATIONS ABOUT OUR RESEARCH

Viguera, A.C., Vanderkruik, R., Gaccione, P. et al. Breastfeeding practices among women taking second-generation antipsychotics: findings from the National Pregnancy Registry for Atypical Antipsychotics. *Arch Womens Ment Health* (2021).

Viguera AC, Freeman MP, Góez-Mogollón L, et al. Reproductive safety of second-generation antipsychotics: updated data from the Massachusetts General Hospital National Pregnancy Registry for Atypical Antipsychotics. *J Clin Psychiatry*. 2021;82(4):20m13745.

Freeman, M.P., Viguera, A.C., Góez-Mogollón, L. et al. Reproductive safety of aripiprazole: data from the Massachusetts General Hospital National Pregnancy Registry for Atypical Antipsychotics. *Arch Womens Ment Health* 24, 659–667 (2021).

Baker AS, Wales R, Noe O, Gaccione P, Freeman MP, Cohen LS. The Course of ADHD during Pregnancy. *Journal of Attention Disorders*. December 2020.

Joffe, H., de Wit, A., Coborn, J., Crawford, S., Freeman, M., Wiley, A., Athappilly, G., Kim, S., Sullivan, K.A., Cohen, L.S. and Hall, J.E., 2019. Impact of estradiol variability and progesterone on mood in perimenopausal women with depressive symptoms. *The Journal of Clinical Endocrinology & Metabolism*. 2019 Nov 6. dgz181

Freeman MP, Goez-Mogollon L, Sosinsky AZ, Church TR, McElheny SA, Viguera AC, Cohen LS. The impact of obesity on pregnancy outcomes among women with psychiatric disorders: Results from a prospective pregnancy registry. *Journal of Psychosomatic Research*. 2019; 123:109735.

Raffi ER, Nonacs R, Cohen LS. Safety of Psychotropic Medications During Pregnancy. *Clinics in Perinatology*. 2019; 46:215-234.

(4) Acitretin 【製薬企業】

T.A.P.P. (Take Action to Prevent Pregnancy)

Teva's Take Action to Prevent Pregnancy (T.A.P.P.)

<https://www.tevagerics.com/acitretin>

(5) Actemra (tocilizumab) 【学会・専門団体】

OTIS Autoimmune Diseases in Pregnancy Study

<https://mothertobaby.org/ongoing-study/actemra-tocilizumab/>

(6) Adderall (amphetamine) 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(7) Afluria Quadrivalent 【製薬企業】

Seqirus Influenza Vaccine Pregnancy Registry

<https://www.seqirus.us/pregnancy-registry?msclkid=ff75570cc4ff11ecbbbe1bb38c76d94a>

Seqirus is one of the world's largest influenza vaccine companies. We were created when our

parent company, CSL Limited, acquired the Novartis influenza vaccine business and combined it with vaccine subsidiary, bioCSL. 100 years of securing healthy lives. Seqirus has a rich heritage in guarding against influenza.

- (8) Aimovig (erenumab) 【CRO・製薬企業】
AIMOVIG Pregnancy Exposure Registry
(Copyright © 2021, IQVIA. All rights reserved)

<https://www.genesispregnancyregistry.com/>

This Website, www.genesispregnancyregistry.com, including any and all platforms built with the intended purpose to use either in conjunction with, in addition to, or in lieu of this Website (hereinafter collectively referred to as “Website”) is owned by IQVIA and managed on behalf of Amgen Inc. This Website is provided for pregnant women who were diagnosed with migraine and have (or have not) taken Aimovig® (erenumab-aooe) shortly before or during pregnancy, to participate in the GENESIS Pregnancy Registry (“study”). The Website enables you to provide personal data in order that you can be contacted by your local Registry Coordinating Center about your eligibility and possible participation in the registry.

- (9) Ajoovy (fremanezumab) 【製薬企業】
Teva Migraine Pregnancy Registry

<https://tevamigrainepregnancyregistry.com/>

(4)と同じ企業

- (10) Aldurazyme (laronidase) 【製薬企業】
MPSI Registry (Sanofi Genzyme Rare Disease Registries)

<https://www.registrynxt.com/>



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(11) Ambien (zolpidem) 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(12) Anafranil (clomipramine) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(13) Aptiom (eslicarbazepine acetate) 【医療機関】

North American AED Pregnancy Registry

<https://www.aedpregnancyregistry.org/>

The North American AED Pregnancy Registry / The Massachusetts General Hospital
128 Nashua Street | Suite 8438, Boston, MA 02114 – Toll Free 1.888.233.2334

Sponsored by: Abbvie, AdVanz, Janssen, Greenwich Biosciences, Pfizer, Sunovian, UCB, Zogenix, Supernus

(14) Arava (leflunomide) 【学会・専門団体】

Leflunomide Pregnancy Registry
OTIS Autoimmune Diseases in Pregnancy Study
(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/arava-leflunomide/>

- (15) Aristada (aripiprazole lauroxil) 【医療機関・医科大学】
National Pregnancy Registry for Psychiatric Medications
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>
- (16) Asendin (amoxapine) 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>
- (17) Aubagio (teriflunomide) 【学会・専門団体】
OTIS Autoimmune Diseases in Pregnancy Study
(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/aubagio-teriflunomide/>
- (18) Benlysta (belimumab) 【製薬企業】
Benlysta Pregnancy Registry / GlaxoSmithKline

<http://pregnancyregistry.gsk.com/belimumab.html>
- (19) Bexsero (Meningococcal Group B Vaccine) 【製薬企業】
Bexsero Pregnancy Registry / GlaxoSmithKline : PPD, Inc.(臨床研究サービス企業)

<https://pregnancyregistry.gsk.com/bexsero.html?msclkid=f0916e0fc51711ec9cd447ecc4b3a5a5>

(20) Brintellix (vortioxetine) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(21) **Celexa (citalopram)** 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(22) Cellcept (mycophenolate) 【REMS・製薬企業】

Mycophenolate Pregnancy Registry
Transplantation Pregnancy Registry International

<https://www.mycophenolaterems.com/#Main>



What is the Mycophenolate REMS ?

The Mycophenolate REMS is a program to tell doctors, nurses, pharmacists, and patients about the increase risk to taking mycophenolate during pregnancy. It was require by the Hood Drug Administration (FDA)

CellCept by Genentech USA, Inc.

Myfortic by Novartis Pharmaceuticals Corporation.

& Generic formuration by Many Pharmaceutical Companies

This Web site was developed as a service provided by the manufacturers of mycophenolate-containing products participating in the Mycophenolate REMS.

<https://www.mycophenolaterems.com/#Main/LegalStatement>

- (23) Cimzia (certolizumab pegol) **【学会・専門団体】**
OTIS Autoimmune Diseases in Pregnancy Study
(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/cimzia-certolizumab-pegol/>
- (24) Clozaril (clozapine) **【医療機関・医科大学】**
National Pregnancy Registry for Atypical Antipsychotics
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>
- (25) Comirnaty (Pfizer BioNTech COVID-19 vaccine) **【学会・専門団体】**
Organization of Teratology Information Specialists (OTIS) Exposure Registry and
Diseases in Pregnancy Study
(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/covid19-vaccines/>
- (26) Concerta Daytrana (methylphenidate) **【医療機関・医科大学】**
National Pregnancy Registry for Psychostimulants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>
- (27) COVID-19 Vaccines (multiple products) **【医療機関・医科大学】**
COVID-19 Vaccine in Pregnancy and Lactation: Registry to Explore Immunization
Practices, Outcomes and Quality Improvement Initiatives

<https://redcap.iths.org/surveys/?s=87JFRCL8R8>

You are invited to participate in an online registry of persons who receive the COVID-19 vaccine and who are also pregnant, postpartum, lactating and/or contemplating pregnancy. This is a registry that has been developed by Dr. Alisa Kachikis and other investigators in the University of Washington Department of Obstetrics and Gynecology. It should take approximately 3 minutes to register your information.

(28) Desoxyn (Methamphetamine HCl) 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(29) Desyrel (trazodone) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(30) Dexedrine (dextroamphetamine) 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(31) Dojolvi (triheptanoin) 【製薬企業】

Long-Chain Fatty Acid Oxidation Disorders In-Clinic Disease Monitoring Program

<https://www.clinicaltrials.gov/ct2/show/NCT04632953>

医師・患者ともに電話受付のみ(上記ホームページは clinicaltrial.com)

Sponsor : Ultragenyx Pharmaceutical Inc

Information provided by (Responsible Party) : Ultragenyx Pharmaceutical Inc

Ultragenyx Treatment of Rare and Ultra-Rare Genetic Diseases

<https://www.ultragenyx.com/?msclkid=a9103540c52111eca91b01ffa3413930>

Ultragenyx Pharmaceutical 社が発売している 3 医薬品の添付文書には、Pregnancy Registry に関する記載なし。

(32) Doral (quazepam) 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(33) Dupixent (dupilumab) 【学会・専門団体】

Organization of Teratology Information Specialists (OTIS) Exposure Registry and Diseases in Pregnancy Study

(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/dupixent-dupilumab%e2%80%8e/>

(34) Effexor (venlafaxine) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(35) Effexor XR (Venlafaxine Hydrochloride) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(36) Elavil (amitriptyline) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(37) Emgality (galcanezumab) 【製薬企業】

Migraine Pregnancy Registry (Lilly) . . . coming soon

<https://migrainepregnancyregistry.com/>

(38) Emsam (selegiline) 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(39) Entyvio (vedolizumab) 【学会・専門団体】

OTIS Autoimmune Diseases in Pregnancy Study

(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/entyvio-vedolizumab/>

(40) Epidiolex (cannabidiol) 【医療機関】
Antiepileptic Drug Pregnancy Registry

<https://www.aedpregnancyregistry.org/>

The North American AED Pregnancy Registry / The Massachusetts General Hospital

128 Nashua Street | Suite 8438, Boston, MA 02114 – Toll Free 1.888.233.2334

Sponsored by: Abbvie, AdVanz, Janssen, Greenwich Biosciences, Pfizer, Sunovion, UCB, Zogenix, Supernus

(41) Fabrazyme (agalsidase beta) Fabry Disease 【製薬企業】
Fabry Registry / Genzyme Corporation



<https://www.registrynxt.com/>

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(42) Fanapt (iloperidone) Mental Health Disorders 【医療機関・医科大学】
National Pregnancy Registry for Atypical Antipsychotics
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(43) Fasenra (benralizumab) Asthma 【学会・専門団体】
The Benralizumab Pregnancy Exposure Study: OTIS Vaccines and Medications in Pregnancy Surveillance Study (VAMPSS)
(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/fasenra-benralizumab/>

- (44) Fetzima (levomilnacipran) Depression 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (45) Fintepla (fenfluramine) Oral Solution Epilepsy 【医療機関】
Antiepileptic Drug Pregnancy Registry

<https://www.aedpregnancyregistry.org/>

The North American AED Pregnancy Registry / The Massachusetts General Hospital

128 Nashua Street | Suite 8438, Boston, MA 02114 – Toll Free 1.888.233.2334

Sponsored by: Abbvie, AdVanz, Janssen, Greenwich Biosciences, Pfizer, Sunovion, UCB, Zogenix, Supernus

- (46) Firdapse (amifampridine) Lambert-Eaton Myasthenic Syndrome 【製薬企業】
Pregnancy Surveillance Program of Women and Infants Exposed to Firdapse During Pregnancy

<https://firdapsepregnancystudy.com/>

The FIRDAPSE Pregnancy Registry is an observational study that Catalyst Pharmaceuticals, Inc., is conducting to follow patients who have been exposed to at least one dose of FIRDAPSE® at any time during pregnancy, and their infants up through 1 year of age.

Pregnant women with a diagnosis of Lambert Eaton myasthenic syndrome (LEMS), who have not been exposed to FIRDAPSE, are also eligible for this pregnancy registry.

Your participation in this study will help Catalyst Pharmaceuticals, Inc. determine if there are any effects of FIRDAPSE on pregnant women or their children. The study data will be provided to the U.S. Food and Drug Administration (FDA) so that other women who become pregnant while being treated with FIRDAPSE can better understand the effects FIRDAPSE might have on pregnancies and birth defects.

(47) Fluoxetine (Fluoxetine Hydrochloride) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(48) Focalin (Dextroamphetamine) ADD/ADHD 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(49) Forfivo (Bupropion Hydrochloride) Depression 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(50) Galafold (migalastat) Fabry Disease 【製薬企業】

A Global Prospective Observational Study of Women with Fabry Disease and Their Infants During Pregnancy and Breastfeeding

<https://www.fabrypregnancyregistry.com/>

The registry is an observational, prospective, retrospective pregnancy and breastfeeding study that Amicus Therapeutics Inc. is conducting. The aim of this registry is to collect valuable health information regarding the pregnancies and/or breastfeeding of women who have Fabry disease and their infants up through 1 year of age. Amicus Therapeutics, Inc. is

working with United BioSource LLC (UBC), a company with a Pregnancy Coordinating Center, which will collect all registry health information.

- (51) Geodon (ziprasidone) Mental Health Disorders 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (52) Gilenya (fingolimod) Multiple Sclerosis 【製薬企業】
The Gilenya Pregnancy Registry

<https://clinicaltrials.gov/ct2/show/NCT01285479>

上記ホームページは Clinical trials.com

<https://www.recruiting-trials.novartis.com/clinicaltrials/study/nct01285479?msclkid=3fb6dc23c5d211eca2f63e23386dffab>

The purpose of the Multi-National Gilenya Pregnancy Exposure Registry in Multiple Sclerosis (MS) is to continuously monitor, evaluate, and assess for major and minor teratogenic effects in the offspring of women exposed to Gilenya before (up to 8 weeks before last menstrual period) and during pregnancy in routine clinical practice. The overall aim is to collect and evaluate data on maternal, fetal, and infant outcomes and compare it with reference populations.

Novartis Investigative Site Recruiting Fort Lauderdale, 33308, Florida, United States

- (53) Halcion (triazolam) Insomnia 【医療機関・医科大学】
National Pregnancy Registry for Psychiatric Medications
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (54) HEPLISAV-B (Recombinant, Adjuvanted) 【製薬企業】
HEPLISAV-B [Hepatitis B Vaccine (Recombinant), Adjuvanted] Pregnancy Registry

<https://heplisavbpregnancyregistry.com/?msclkid=227c2efbc5d411ecb21f531a20769ed6>

The HEPLISAV-B Pregnancy Registry is an observational research study for women who were vaccinated with HEPLISAV-B within 28 days prior to conception, or during their pregnancy. The goal of the registry is to learn more about the health of infants born to mothers exposed to HEPLISAV-B during pregnancy. The information collected will provide doctors with an understanding of the effect (if any) of HEPLISAV-B exposure during pregnancy.

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- (55) Ilumya (tildrakizumab) Psoriasis 【学会・専門団体】
Organization of Teratology Information Specialists (OTIS) Autoimmune Diseases in Pregnancy Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/ilumya-tildrakizumab-asmn/>

- (56) Invega (paliperidone) Mental Health Disorders 【医療機関・医科大学】
National Pregnancy Registry for Atypical Antipsychotics
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (57) Janumet (sitagliptin phosphate plus metformin hydrochloride)
Type 2 Diabetes 【製薬企業】
Merck Pregnancy Registry Program

<https://www.merckpregnancyregistries.com/januvia.html>

The Pregnancy Registry for JANUVIA and JANUMET receives voluntary reports from healthcare providers or from women/family members/friends about women who inadvertently (before knowing they were pregnant) or purposefully (knowingly took the drug to control their diabetes) used JANUVIA or JANUMET during pregnancy.

Reports of the aggregate data in the Registry are updated annually and are available to healthcare providers in the United States upon request. (In countries outside the United States, information is available through the local Merck subsidiary). To request a report, call the toll-free number below or download and complete the attached Annual Report Request Form and fax it to the Registry. Please include your fax number. A report will be sent to you within 3 business days.

Healthcare providers are encouraged to report cases of prenatal exposure as early in pregnancy as possible to facilitate the collection of prospective, unbiased information.

- (58) Januvia (sitagliptin phosphate) Type 2 Diabetes 【製薬企業】
Merck Pregnancy Registry Program

<https://www.merckpregnancyregistries.com/januvia.html>

(57)と同じレジストリ組織

- (59) Juxtapid (lomitapide)
Homozygous Familial Hypercholesterolemia 【製薬企業】
Global Lomitapide Pregnancy Exposure Registry

<https://juxtapid.com/>

上記は、企業の製品ホームページ Pregnancy Registry 情報は見いだせない

<https://trialbulletin.com/lib/entry/ct-02399839>

Lead Sponsor Amryt Pharma

Provider of Information About this Clinical Study Sponsor

Overall Official(s) Sallyann O'Brien, Study Director, Amryt Pharmaceuticals

- (60) Kevzara (sarilumab) Rheumatoid Arthritis 【学会・専門団体】

Organization of Teratology Information Specialists (OTIS) Autoimmune Diseases in Pregnancy Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/kevzara-sarilumab/>

(61) Latuda (lurasidone) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(62) Lexapro (escitalopram) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(63) Ludiomil (maprotiline) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(64) Lunesta (eszopiclone) Depression 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (65) Luvox (fluvoxamine) Depression 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (66) Lyrica (pregabalin) Epilepsy 【医療機関】
Antiepileptic Drug Pregnancy Registry

<https://www.aedpregnancyregistry.org/>

The North American AED Pregnancy Registry / The Massachusetts General Hospital
128 Nashua Street | Suite 8438, Boston, MA 02114 – Toll Free 1.888.233.2334
Sponsored by: Abbvie, AdVanz, Janssen, Greenwich Biosciences, Pfizer, Sunovion, UCB,
Zogenix, Supernus

- (67) Marplan (Isocarboxazid) Depression 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (68) Mavenclad (cladribine tablets) Multiple Sclerosis 【製薬企業】
Worldwide pregnancy surveillance program of oral cladribine - MAPLE-MS

MS LifeLines is a registered trademark of Merck KGaA, Darmstadt, Germany or its affiliates.

(69) Mayzent (siponimod) Multiple Sclerosis 【学会・専門団体】
Organization of Teratology Information Specialists (OTIS) Exposure Registry and Diseases
in Pregnancy Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/mayzent-siponimod/>

(70) Menactra (meningococcal polysaccharide diphtheria toxoid) Vaccine
Menactra vaccine Pregnancy Registry 【製薬企業】

<https://www.sanofipasteurpregnancyregistry.com/?fa=menactra>

The Menactra Pregnancy Registry utilizes passive surveillance to monitor pregnancy exposures to Menactra. All pregnant women who received the Menactra vaccine during pregnancy or within the 30 days following their last menstrual period are eligible for inclusion. The objective of the Menactra pregnancy registry is to monitor and evaluate all submitted reports of vaccine exposure during pregnancy, as well as maternal, obstetrical, pregnancy, neonatal and infant outcomes. Enrollment in the Menactra pregnancy registry should occur as soon as possible following the vaccination, and ideally prior to any pre-natal testing.

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(71) MenQuadfi meningococcal (Groups A, C, Y, W) conjugate vaccine Vaccine
MenQuadfi Vaccine Pregnancy Registry 【製薬企業】

The Sanofi Pasteur Pregnancy Registries are an organized, systematic collection of data on pregnant women vaccinated with one or more of the following vaccines:

- Menactra® (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine)
- Adacel® (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed)
- Fluzone® Quadrivalent (Influenza Virus Vaccine)
- MenQuadfi® (Meningococcal [groups A, C, Y, W] conjugate vaccine)
- Dengvaxia® (Dengue tetravalent vaccine, live, attenuated)

- Flublok® Quadrivalent (Influenza Virus Vaccine)

The Sanofi Pasteur pregnancy registries are part of the companies passive surveillance programs designed to collect and evaluate all voluntary reports of pregnancy exposure to Menactra®, Adacel®, Fluzone® Quadrivalent, MenQuadfi®, Dengvaxia® and Flublok® Quadrivalent vaccines as well as maternal, pregnancy, obstetrical, neonatal and infant outcomes to monitor for potential safety events that may arise in this population.

- (72) Metadate CD Methylin (methylphenidate HCL) ADD/ADHD 【医療機関・医科大学】
National Pregnancy Registry for Psychostimulants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (73) Motegrity (prucalopride) 【学会・専門団体】
Functional Constipation (Chronic idiopathic constipation (CID) or Irritable bowel disease – Constipation (IBS-C))

Organization of Teratology Information Specialists (OTIS) Exposure Registry and Diseases in Pregnancy Study

- (5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/motegrity-prucalopride/>

- (74) Multiple Drugs COVID-19
COVID-19 International Drug Pregnancy Registry (COVID-PR)

<https://covid-pr.pregistry.com/>

The COVID-PR is a research study that focuses on gathering information. We are asking women who were treated for COVID-19 during pregnancy to answer questions about their pregnancies, their health, and their babies' health. Asking questions and collecting information from pregnant women themselves provides a unique perspective from other

studies that rely on doctors or nurses to provide information about their pregnant patients.

(75) Multiple Drugs Epilepsy 【医療機関】
AED (Antiepileptic Drug) Pregnancy Registry

<https://www.aedpregnancyregistry.org/>

The North American AED Pregnancy Registry / The Massachusetts General Hospital

128 Nashua Street | Suite 8438, Boston, MA 02114 – Toll Free 1.888.233.2334

Sponsored by: Abbvie, AdVanz, Janssen, Greenwich Biosciences, Pfizer, Sunovion, UCB, Zogenix, Supernus

(76) Multiple Drugs Autoimmune Diseases 【学会・専門団体】
Crohn's Disease, Rheumatoid Arthritis, Psoriasis, Psoriatic Arthritis, Multiple Sclerosis (MS),
Ulcerative Colitis

OTIS AutoImmune Diseases in Pregnancy Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/pregnancy-studies/>

(77) Multiple Drugs Asthma 【学会・専門団体】
OTIS Vaccines and Medications in Pregnancy Surveillance Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/pregnancy-studies/>

(78) Multiple Drugs Cancer 【医科大学】
Cancer and Childbirth Registry

<https://cancerandpregnancy.com/>

This is the purpose of the Cancer and Pregnancy Registry maintained at Cooper Medical School at Rowan University. Accumulating data on how women are diagnosed and treated internationally is analyzed to note trends in diagnostic delays in pregnancy to recommend improvements, and to collect long term outcome data for the mother and neonate to publish treatment choices which are safest for the mother and child.

(79) Multiple Drugs HIV/AIDS
Antiretroviral Pregnancy Registry

<http://www.apregistry.com/Default.aspx>

Syneos Health ("we," "us," or "Syneos Health"), operating through its affiliates/subsidiaries located throughout the world (collectively, the "Company") is committed to protecting your privacy and has implemented the measures below to protect the personal data we process about you ("Personal Data").

Syneos Health is an end-to-end, fully integrated Business-to-Business solutions company primarily servicing the biopharmaceutical industry.

(80) Multiple Drugs Anti-rejection Medicines
Transplantation Pregnancy Registry International

【医療機関・学会】

<https://www.transplantpregnancyregistry.org/>

The National Transplantation Pregnancy Registry (NTPR) was established by Dr. Vincent Armenti at Thomas Jefferson University in Philadelphia, PA in 1991 to study the outcomes of pregnancies in any solid organ transplant recipients in North America. Shortly afterwards, the NTPR was introduced in a letter to the editor in the American Journal of Kidney Diseases and through questionnaires disbursed by our founding sponsor, Sandoz Pharmaceuticals (now Novartis), the transplant community embraced the need for such research through robust referrals to the NTPR. Since its inception, over 2800 transplant recipients have shared information with the Registry regarding over 5000 pregnancy outcomes. Each year, our study coordinators speak with hundreds of current and future mothers and fathers who are transplant recipients and to their healthcare providers.

(81) Mycophenolate Immunosuppressive drug 【REMS・製薬企業】

Mycophenolate Pregnancy Registry

Transplantation Pregnancy Registry International

(22)と同じ REMS に基づくレジストリ

<https://www.mycophenolaterems.com/#Main>



What is the Mycophenolate REMS ?

The Mycophenolate REMS is a program to tell doctors, nurses, pharmacists, and patients about the increase risk to taking mycophenolate during pregnancy. It was require by the Food Drug Administration (FDA)

CellCept by Genentech USA, Inc.

Myfortic by Novartis Pharmaceuticals Corporation.

& Generic formuration by Many Pharmaceutical Companies

This Web site was developed as a service provided by the manufacturers of mycophenolate-containing products participating in the Mycophenolate REMS.

<https://www.mycophenolaterems.com/#Main/LegalStatement>

(82) Myfortic Immunosuppressive drug 【REMS・製薬企業】

Mycophenolate Pregnancy Registry

Transplantation Pregnancy Registry International

(22)と同じ REMS に基づくレジストリ

<https://www.mycophenolaterems.com/#Main>



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& Generic formulation by Many Pharmaceutical Companies

This Web site was developed as a service provided by the manufacturers of mycophenolate-containing products participating in the Mycophenolate REMS.

<https://www.mycophenolaterems.com/#Main/LegalStatement>

(83) Myozyme (alglucosidase alfa) Pompe Disease (GAA deficiency) 【製薬企業】
Pompe Disease Registry

<https://www.registrynxt.com/>



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(41)と同じスポンサー、調査受託会社、デジタルプラットフォーム制作管理企業

(84) Naglazyme 【製薬企業】
Maroteaux-Lamy Syndrome also known as Polydystrophic Dwarfism or
Mucopolysaccharidosis VI
MPS VI Clinical Surveillance Program (CSP)

<https://clinicaltrials.gov/ct2/show/NCT00214773>

<https://www.medfind.com/articles/clinical-trial/7155268?msclid=0b3bcd78c68711ec8ee4fde03f87fdd3>

<https://www.biomarin.com/clinical-trials/mps-vi/?msclid=0b3c5177c68711ec922df4e19c2cbf0a>

The objectives of this program are: to further characterize the natural progression of MPS VI disease; to generate and disseminate information on the care and management of MPS VI patients to clinical and medical professionals; to provide a resource to physicians and patients by providing information for optimizing patient care based on aggregate data; to characterize

the clinical response to long-term Naglazyme® (galsulfase) treatment; to further characterize the long-term safety of Naglazyme® treatment.

Study Director : Julie Johnson BioMarin Pharmaceutical

Sponsors and Collaborators : BioMarin Pharmaceutical

(85) Nardil (phenelzine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(86) Nexletol; Nexlizet (bempedoic acid) High cholesterol 【製薬企業】

[heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD)]

Bempedoic Acid Pregnancy Surveillance Program

<https://clinicaltrials.gov/ct2/show/NCT05103254>

<https://www.ppd.com/our-solutions/clinical/peri-and-post-approval/non-interventional-studies/pregnancy-and-lactation-studies/?msckid=0d50efaac68911ec93312f1b16c0909c>

Sponsors and Collaborators Esperion Therapeutics, Inc.

Investigators Study Director : Michael Louie, M.D Esperion Therapeutics

Evidera, PPD business unit

(87) Norpramin (desipramine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (88) Nucala (mepolizumab) Asthma 【学会・専門団体】
The Mepolizumab Pregnancy Exposure Registry
OTIS Vaccines and Medications in Pregnancy Surveillance Study (VAMPSS)
(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/nucala-mepolizumab/>

- (89) Nulojix (belatacept) Immunosuppressive drug 【医療機関・学会】
Transplantation Pregnancy Registry International

<https://www.transplantpregnancyregistry.org/>

The National Transplantation Pregnancy Registry (NTPR) was established by Dr. Vincent Armenti at Thomas Jefferson University in Philadelphia, PA in 1991 to study the outcomes of pregnancies in any solid organ transplant recipients in North America. Shortly afterwards, the NTPR was introduced in a letter to the editor in the American Journal of Kidney Diseases and through questionnaires disbursed by our founding sponsor, Sandoz Pharmaceuticals (now Novartis), the transplant community embraced the need for such research through robust referrals to the NTPR. Since its inception, over 2800 transplant recipients have shared information with the Registry regarding over 5000 pregnancy outcomes. Each year, our study coordinators speak with hundreds of current and future mothers and fathers who are transplant recipients and to their healthcare providers.

- (90) Nurtec ODT (rimegepant) Migraine 【製薬企業】
A Prospective, Registry-based, Observational Study to Assess Maternal, Fetal and Infant Outcomes Following Exposure to Rimegepant
The Migraine Observational Nurtec Pregnancy Registry (MONITOR)

<https://nurtecpregnancyregistry.com/>

A pregnancy registry is a study that collects health information from women who take prescription medicines when they are pregnant. Information is also collected on the newborn baby. This information is compared with women who have not taken medicine during pregnancy.

The goal of the MONITOR Pregnancy Registry is to help doctors, patients, and researchers better understand the safety of Nurtec ODT (rimegepant) and other migraine medications used during pregnancy. Pregnant women in the United States with migraine may be eligible to participate. The study collects health information from enrolled pregnant women and their healthcare providers related to their pregnancies and developing babies up to 1 year of age. Biohaven Pharmaceuticals, Inc. NURTEC and NURTEC ODT are registered trademarks of Biohaven Pharmaceutical Ireland DAC.

- (91) Nuvigil (armodafinil) Excessive sleepiness **【製薬企業】**
Excessive sleepiness associated with: Obstructive Sleep Apnea Hypopnea Syndrome
Narcolepsy Shift Work sleep disorder
Nuvigil Pregnancy Registry

<https://www.nuvigilpregnancyregistry.com/>

The NUVIGIL Pregnancy Registry has been established to evaluate the safety of NUVIGIL use during pregnancy. To learn more about the NUVIGIL Pregnancy Registry, contact a Registry representative at 1-866-404-4106 (toll-free). Cephalon, Inc. a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

- (92) Nuvigil (armodafinil) Mental Health Disorders **【医療機関・医科大学】**
National Pregnancy Registry for Psychiatric Medications
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (93) Ocrevus (ocrelizumab) Multiple Sclerosis **【CRO・製薬企業】**
Ocrevus Pregnancy Registry

<https://www.ocrevuspregnancyregistry.com/>

The OCREVUS Pregnancy Registry is a global registry for women with MS who are pregnant

and have or have not received OCREVUS (ocrelizumab). The purpose of this pregnancy registry is to learn more about the health of pregnant women who have or have not received ocrelizumab and the health of their babies. This will be done by monitoring participants throughout their pregnancy, followed by monitoring the health of their babies until they are at least 12 months old.

Because of this registry, pregnant women who are exposed to ocrelizumab in the future may have more information about how their pregnancies and babies may or may not be affected. This website www.ocrevuspregnancyregistry.com, including any and all platforms built with the intended purpose to use either in conjunction with, in addition to, or in lieu of this website (hereinafter collectively referred to as "Website") is owned by IQVIA™ and managed on behalf of F. Hoffmann-La Roche Ltd ("Roche"). This Website is provided to enable women with multiple sclerosis ("MS") who are pregnant and either have or have not received OCREVUS during or within 6 months before their pregnancy, to participate in the Ocrevus® Pregnancy Registry Study ("Study"). The website enables you to provide personal data in order that you can be contacted by your local Registry Coordinating Center about your eligibility and possible participation in the study.

<https://www.ocrevuspregnancyregistry.com/Privacy-Policy>

(94) Onpattro (patisiran) hATTR Amyloidosis 【CRO・製薬企業】

Onpattro Pregnancy Exposure Registry

電話調査のみ

<https://www.onpattrohcp.com/safety-profile?msclkid=16eec96fc69311ec918431f442cd3034>

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ONPATTRO during pregnancy. Physicians are encouraged to enroll pregnant patients, or pregnant women may register themselves in the program by calling 1-877-256-9526 or by contacting alnylampregnancyprogram@iqvia.com.

ONPATTRO and Alnylam Assist are registered trademarks of Alnylam Pharmaceuticals, Inc

(95) Orencia (abatacept) Auto Immune Diseases 【学会・専門団体】

OTIS AutoImmune Diseases in Pregnancy Study

(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/orencia/>

(96) Oriahnn (elagolix/estradiol/norethindrone acetate and elagolix)

【CRO・製薬企業】

Heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women

Prospective Registry to Evaluate Pregnancy Outcomes in Women Treated with Elagolix

<https://www.bloompregnancyregistry.com/>

The BLOOM Pregnancy Registry is a North American registry for pregnant women who have endometriosis and who may or may not have taken Orilissa® (elagolix) during pregnancy. By sharing your experience, you could help doctors to better understand Orilissa use before and during pregnancy. Doctors have questions about whether it has any effect on pregnancy, delivery, or the health of babies of women who were taking it when they became pregnant. The possible effects will be compared with outcomes for women who were not taking Orilissa when they became pregnant but who also have endometriosis. Participants will be followed throughout their pregnancy; information on the health of participants' babies will also be collected until the baby is 12 months old.

By joining this registry and sharing your information, in the future, pregnant women who are exposed to Orilissa may have more information about how their pregnancies and babies may or may not be affected.

Are you pregnant? Do you have endometriosis and/or have you taken Orilissa® (elagolix) prescribed by your doctor? If so, you may be able to take part in a North American pregnancy registry. Some eligible women will have taken Orilissa during early pregnancy, before realizing they were pregnant. However, you do not have to have taken Orilissa to participate.

This website, www.bloompregnancyregistry.com, including any and all platforms built with the intended purpose to use either in conjunction with, in addition to, or in lieu of this website (hereinafter collectively referred to as "Website") is owned by IQVIA and managed on behalf of AbbVie Inc. This Website is provided for pregnant women who have endometriosis and/or who have taken Orilissa® (elagolix) during pregnancy, to participate in the BLOOM

Pregnancy Registry (“study”). The Website enables you to provide personal data in order that you can be contacted by your local Registry Coordinating Center about your eligibility and possible participation in the registry.

<https://www.bloompregnancyregistry.com/Privacy-Policy>

- (97) Orilissa (elagolix) 【CRO・製薬企業】
Moderate to Severe Pain Associated with Endometriosis
Prospective Registry to Evaluate Pregnancy Outcomes in Women Treated with Elagolix

<https://clinicaltrials.gov/ct2/show/NCT04464187>

Sponsors and Collaborators : ABBVIE

Investigators : Study Director ABBVIE inc. AbbVie

- (98) Otezla (apremilast) Psoriatic Arthritis, Psoriasis 【学会・専門団体】
OTIS AutoImmune Diseases in Pregnancy Study
(5) と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/otezla-apremilast/>

- (99) Palforzia Peanut [Arachis hypogaea] Allergen Powder- dnfp 【製薬企業】
Peanut Allergy
Palforzia Pregnancy Registry (No webpage available)

Animal studies are not available. There are no controlled data in human pregnancy. The background birth defect and miscarriage risk for the indicated population is not known. In the US general population, the estimated major birth defect risk is 2 to 4% and the miscarriage risk is 15 to 20%.

A pregnancy registry monitoring outcomes of exposures during pregnancy is available. Healthcare providers are encouraged to contact Aimmune at 1-833-246-2566.

Aimmune Therapeutics is a biopharmaceutical company developing and bringing new treatments to people with potentially life-threatening food allergies.

<https://www.aimmune.com/about>

(100) Pamelor (nortriptyline) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(101) Parnate (tranylcypromine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(102) Paxil (paroxetine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(103) Plegridy (Peginterferon beta-1a) Multiple Sclerosis

PLEGnancy

【疾患関連協会(患者・家族・専門家)】

<https://www.plegridypregnancyregistry.com/>

最終確認日：2022年3月28日(403 Forbidden と表示され確認不能)

<https://www.nationalmssociety.org/Living-Well-With-MS/Diet-Exercise-Healthy-Behaviors/Womens-Health/Pregnancy/Pregnancy-Registration?msclkid=6c09579ec6b011eca771e0de2dd6d7ed>

最終確認日：2022年3月28日

When Sylvia Lawry's brother, Bernard, began experiencing visual and balance problems in 1945, she and her sister Alice placed a classified advertisement in The New York Times: "Multiple sclerosis. Will anyone recovered from it please communicate with patient." The sisters received 54 replies from people as desperate as they were. Most asked to be informed if the two heard anything promising. "I was looking for medical clues that might have helped my brother," Ms. Lawry said in an interview with The New York Post in 1959. "But when the responses started to snowball and come from all over the country, I decided to give up the law and let my creative energies spill over into helping people with MS."

Sylvia realized the need for an organized effort to encourage and finance research into the cause, treatment and cure of multiple sclerosis. On March 11, 1946, Ms. Lawry, a young woman without a scientific background, gathered 20 of the nation's most prominent research scientists and medical experts and founded what would become the National Multiple Sclerosis Society. Her passion and perseverance launched a movement that's led to more breakthroughs than the world has seen for any other neurological disease.

The National MS Society brings the MS movement together—and turns our power and passion into real results. When the Society was founded more than 75 years ago, MS was neglected and poorly understood. What began as one woman's vision and commitment is now a nationwide organization leading the global charge to create a world free of MS.

RWE Solutions

Plegridy® Registry - - Although Plegridy is not approved for use in pregnancy, a registry has been established to monitor pregnancy and infant outcomes of pregnant women exposed to Plegridy. Physicians are encouraged to enroll pregnant women in the Plegridy pregnancy registry, or women can enroll themselves by calling 1 - 866 - 810 - 1462 or visiting the Plegridy pregnancy registry website .

(104) Praluent (alirocumab) High cholesterol **【製薬企業】**
(heterozygous familial hypercholesterolemia, atherosclerotic cardiovascular disease
(ASCVD), homozygous familial hypercholesterolemia)
Praluent (alirocumab) Descriptive Pregnancy Study
[no webpage]

Sponsors and Collaborators : Regeneron Pharmaceuticals, Sanofi

Investigators : Study Director : Clinical Sciences & Operations Sanfy

(105) Pristiq (desvenlafaxine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(106) Prolia (denosumab) osteoporosis 【製薬企業】

Amgen's Pregnancy Surveillance Program

<http://www.amgenpregnancy.com/en-us/patient/home.aspx>

URL 確認できず

製造販売元 : Amgen Inc

(107) Promacta (eltrombopag) Thrombocytopenia 【製薬企業】

Promacta Pregnancy Registry

GlaxoSmithKline Pregnancy Registry

※ホームページなし

Since Idiopathic Thrombocytopenic Purpura (ITP) affects women who are of reproductive capacity and taking into account the lack of data concerning Eltrombopag (Promacta) use during pregnancy, the Eltrombopag (Promacta) Registry will be an essential component of the ongoing risk management for Eltrombopag (Promacta).

Sponsors and Collaborators : GlaxoSmithKline

Study Director: GSK Clinical Trials, GlaxoSmithKline

(108) Provigil (modafinil) Excessive sleepiness 【製薬企業】

Excessive sleepiness associated with : Obstructive Sleep Apnea Hypopnea Syndrome

Narcolepsy Shift Work sleep disorder

Provigil Pregnancy Registry

<https://www.provigilpregnancyregistry.com/>

The PROVIGIL Pregnancy Registry has been established to evaluate the safety of PROVIGIL use during pregnancy. To learn more about the PROVIGIL Pregnancy Registry, contact a Registry representative at 1-866-404-4106 (toll-free).

Cephalon, Inc. a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd

(109) Provigil (modafinil) ADD/ADHD 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(110) Prozac (fluoxetine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(111) Remeron (mirtazapine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(112) Repatha (evolocumab) High cholesterol 【製薬企業】

heterozygous familial hypercholesterolemia, atherosclerotic cardiovascular disease (ASCVD),
homozygous familial hypercholesterolemia

ホームページなし

An Observational Case Series to Describe Women Exposed to Repatha During Pregnancy
Infant Outcomes During the First Year of Life

AMGEN

(113) Restoril (temazepam) Insomnia 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(114) Rexulti (brexpiprazole) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(115) Risperdal (risperidone) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(116) Ritalin (methylphenidate HCL) ADD/ADHD 【医療機関・医科大学】

National Pregnancy Registry for Psychostimulants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(117) Saphris (asenapine) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(118) Savella Fibromyalgia

【製薬企業】

Savella Pregnancy Registry

<https://www.savellapregnancyregistry.com/>

The purpose of the Savella Pregnancy Registry is to gain knowledge of the effects of taking Savella during pregnancy. Enrollment in the Registry is voluntary, and may help future mothers better understand the risks and benefits of using Savella during pregnancy.

Syneos Health (“we” “us”, or “Syneos Health”), operating through its affiliates/subsidiaries located throughout the world (collectively, the “Company”) is strongly committed to protecting your privacy and has implemented the below to ensure all the personal data you provide is protected.

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization purpose-built to accelerate customer success. We lead with a product development mindset, strategically blending clinical development, medical affairs and commercial capabilities to address modern market realities. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers’ delivery of important therapies to patients. We support a diverse, equitable and inclusive culture

(119) Seroquel (quetiapine) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(120) Serzone (nefazodone) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(121) Sinequan (doxepin) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(122) Skyrizi (risankizumab-rzaa) Psoriasis 【製薬企業】

The GLOW Pregnancy Registry: A prospective observational study on the safety of risankizumab exposure in pregnant women and their offspring

<https://glowpregnancyregistry.com/>

The goal of the GLOW Pregnancy Registry is to help doctors, patients, and researchers better understand the safety of SKYRIZI® (risankizumab-rzaa) and other plaque psoriasis medications when used during pregnancy. Pregnant women in the United States with plaque psoriasis may be eligible to participate. The study collects health information from enrolled pregnant women and their healthcare providers related to their pregnancies and developing babies up to 1 year of age.

(123) Spravato (esketamine) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(124) Stelara (ustekinumab) Psoriatic Arthritis Psoriasis 【学会・専門団体】

OTIS Autoimmune Diseases in Pregnancy Study

MotherToBaby Pregnancy Studies conducted by the Organization of Teratology

Information Specialists (OTIS)

(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/stelara/>

(125) Surmontil (trimipramine) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(126) Symbyax (olanzapine & fluoxetine) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(127) Taltz (ixekizumab) 【製薬企業】

Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Non-radiographic Axial

Spondyloarthritis
Taltz Pregnancy Registry
ホームページなし

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to TALTZ during pregnancy. Pregnant women should be encouraged to enroll themselves in the registry by calling 1-800-284-1695.

Eli Lilly and Company

(128) Tecfidera (dimethyl fumarate) Multiple Sclerosis 【製薬企業】
TecGistry

<https://www.tecfiderapregnancyregistry.com/login>

The TECFIDERA® (dimethyl fumarate) Pregnancy Exposure Registry is a global observational registry of women with MS who have taken TECFIDERA since the first day of their last menstrual period or at any time during pregnancy.

This website www.tecfiderapregnancyregistry.com, including any and all platforms built with the intended purpose to use either in conjunction with, in addition to, or in lieu of this website (hereinafter collectively referred to as “Website”) is owned by IQVIA™ and managed on behalf of Biogen. This Website is provided to enable women who become pregnant while taking Tecfidera or were taking Tecfidera since the first day of their last menstrual period prior to becoming pregnant, to participate in the Tecfidera Pregnancy Exposure Registry study (“TecGistry”). The website enables you to take an online pre-screening questionnaire and provide personal data in order that you can be contacted by your local Registry Coordinating Center about your eligibility and possible participation in TecGistry.

(129) Tegsedi (inotersen) 【製薬企業】

Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (hATTR-PN)
Pregnancy Surveillance Program of Women and Infants Exposed to TEGSEDI During
Pregnancy

<https://www.tegsedipregnancystudy.com/>

he TEGSEDI-PRG pregnancy observational study was developed by Akcea Therapeutics, Inc.

to follow patients who have been exposed to at least one dose of TEGSEDI® (inotersen) during their pregnancy (or patients who became pregnant within 25 weeks of taking TEGSEDI). The purpose of this study is to learn more about the health of pregnant women who are taking or have taken TEGSEDI and the health of their babies.

Pregnant women with the polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN), who have not been exposed to TEGSEDI, are also eligible for this observational pregnancy study.

Your participation in this study will help Akcea Therapeutics Inc. to gather more information that could help women in the future and their doctors make more informed decisions.

(130) Tofranil (imipramine) Depression **【医療機関・医科大学】**

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(131) Tremfya (guselkumab) Psoriasis **【学会・専門団体】**

Organization of Teratology Information Specialists (OTIS) Autoimmune Diseases in Pregnancy Study

MotherToBaby Pregnancy Studies conducted by the Organization of Teratology Information Specialists (OTIS)

(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/tremfya-guselkumab/>

(132) Vibativ (telavancin) Antibacterial for skin infection **【製薬企業】**

Vibativ Pregnancy Registry

<https://clinicaltrials.gov/ct2/show/NCT01130324>

Sponsors and Collaborators : Cumberland Pharmaceuticals

Principal Investigator : Adam Haberle, PhD Cumberland Pharmaceuticals, Inc.

The purpose of this registry is to evaluate the outcome of pregnancy in women exposed to VIBATIV at any time during pregnancy. There are no mandated physician visits for the registry.

(133) Viibryd (Vilazodone Hydrochloride) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(134) Vivactil (protriptyline) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(135) Vyndamax (tafamidis) Transthyretin amyloid cardiomyopathy 【製薬企業】

Tafamidis Enhanced Surveillance for Pregnancy Outcomes (TESPO)

ホームページなし Pfizer

Tafamidis Enhanced Surveillance Pregnancy Outcomes TESPO is a programme to collect safety data, including major birth defects or other developmental abnormalities in live born infants, in female patients with ATTR amyloidosis who are exposed to Vyndaqel during or within 1 month prior to their pregnancy.

(136) Vyndaqel (tafamidis meglumine) Transthyretin amyloid cardiomyopathy 【製薬企業】

Tafamidis Enhanced Surveillance for Pregnancy Outcomes (TESPO)

ホームページなし Pfizer

Tafamidis Enhanced Surveillance Pregnancy Outcomes TESPO is a programme to collect safety data, including major birth defects or other developmental abnormalities in live born infants, in female patients with ATTR amyloidosis who are exposed to Vyndaqel during or within 1 month prior to their pregnancy.

- (137) Vyvanse (lisdexamfetamine dimesylate) ADD/ADHD 【医療機関・医科大学】
National Pregnancy Registry for Psychostimulants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

- (138) WAKIX (pitolisant) Narcolepsy 【製薬企業】
WAKIX Pregnancy Registry – A prospective, observational cohort study designed to evaluate the association between pitolisant exposure during pregnancy and subsequent maternal, fetal, and infant outcomes

<https://www.wakixpregnancyregistry.com/>

The WAKIX Pregnancy Registry has been established to monitor pregnancy outcomes in women who have taken WAKIX during pregnancy.

The purpose of the WAKIX Pregnancy Registry is to learn more about the safety of WAKIX when used during pregnancy.

WAKIX is a registered trademark of Bioprojet Europe, Ltd.

Harmony Biosciences name and logo are registered trademarks.

- (139) Wellbutrin (bupropion) Depression 【医療機関・医科大学】
National Pregnancy Registry for Antidepressants
Massachusetts General Hospital / Harvard Medical School
(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(140) Wellbutrin SR (bupropion Hydrochloride) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(141) Xeljanz (tofacitinib) Rheumatoid Arthritis 【学会・専門団体】

OTIS Autoimmune Diseases in Pregnancy Study

MotherToBaby Pregnancy Studies conducted by the Organization of Teratology Information Specialists (OTIS)

(5)と同じ学会・学術団体

<https://mothertobaby.org/ongoing-study/xeljanz-tofacitinib-citrate/>

(142) Zoloft (sertraline) Depression 【医療機関・医科大学】

National Pregnancy Registry for Antidepressants

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(143) Zulresso (brexanolone) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Psychiatric Medications

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

(144) Zyprexa (olanzapine) Mental Health Disorders 【医療機関・医科大学】

National Pregnancy Registry for Atypical Antipsychotics

Massachusetts General Hospital / Harvard Medical School

(3)と同じレジストリ運営管理組織

<https://womensmentalhealth.org/research/pregnancyregistry/>

以上