

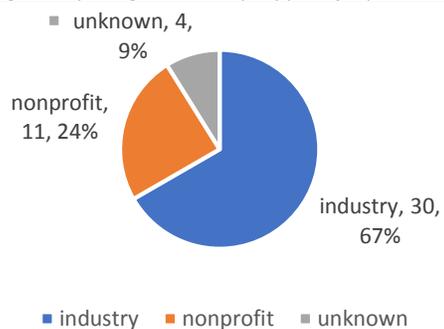
Appendix XII: Pregnancy Registries

Pregnancy exposure registries have been developed to collect health information on exposure to medical products (such as drugs and vaccines) during pregnancy. These databases can be helpful resources for researchers and regulatory agencies. Pregnancy registries were identified based on several sources: a listing provided by the FDA’s Office of Women’s Health¹, publications obtained through literature analysis, and web searches. A list of the pregnancy registries and large databases is provided below.

Summary

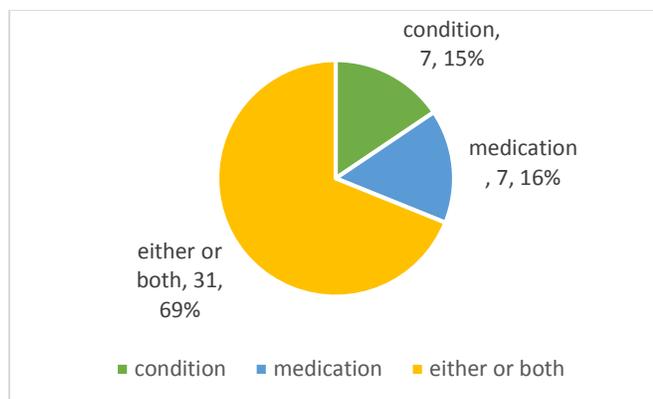
A total of 45 distinct registries were identified. As shown in Figure 1, about two-thirds were sponsored by industry and about one-quarter by nonprofit organizations. Although government organizations may be involved in providing expertise and in encouraging the establishment of registries, government organizations are typically not the sponsor or manager of registries. Several registries did not list a primary sponsor or responsible organization.

Figure 1: Pregnancy Registries, by Type of Sponsoring Organization



Registries may focus on a condition, medication, or both. As shown in Figure 2, most registries determine eligibility based on either medication or condition or both, but some restrict eligibility to only those women taking a specific medication.

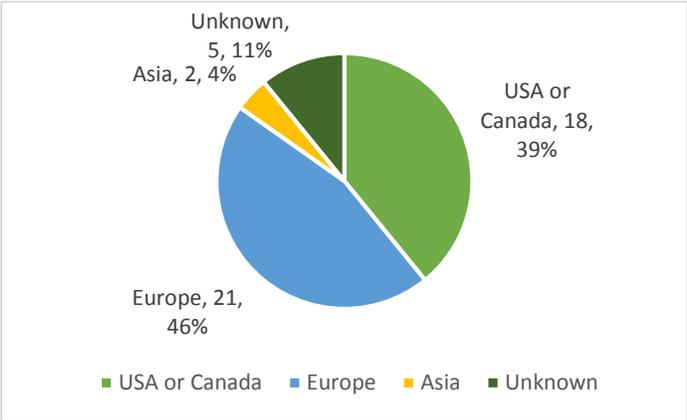
Figure 2: Pregnancy Registries by Eligibility Criteria



¹ <https://www.fda.gov/ScienceResearch/SpecialTopics/WomensHealthResearch/ucm134848.htm>

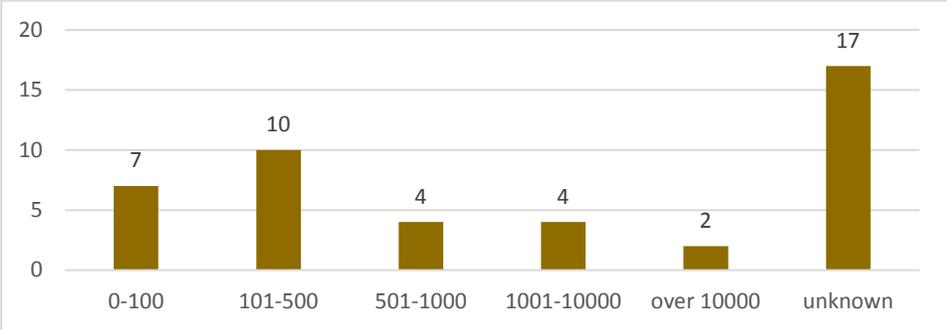
Organizations all over the world sponsor pregnancy registries. Area of origin for the sponsoring organization is shown in Figure 3. Many registries, particularly those based in Europe, accept participants from multiple countries.

Figure 3: Pregnancy Registries by Area of Origin



For over one third of registries, enrollment figures were not provided. For some of the other registries identified, enrollment was very limited. Enrollment numbers are shown in Figure 4.

Figure 4: Number of Pregnancy Registries by Enrollment



List of Pregnancy Registries

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
The North American AED (Antiepileptic Drug) Pregnancy Registry	Multiple Drugs including Aptiom (eslicarbazepine acetate) and Lyrica (pregabalin)	Epilepsy	Massachusetts General Hospital	10,200 (as of May 2016)	1997	http://www.aedpregnancyregistry.org/about-history/
OTIS AutoImmune Diseases in Pregnancy Project	Multiple Drugs including Actemra (tocilizumab), Arava (leflunomide), Aubagio (teriflunomide), Cimzia (certolizumab pegol), Enbrel (etanercept), Entyvio (vedolizumab), Humira (adalimumab), Oencia (abatacept), Otezla (apremilast), Stelara (ustekinumab), Xeljanz (tofacitinib)	Multiple conditions including any approved indication or indication currently in Phase III Trials. Mentioned specifically are multiple sclerosis; Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis; Crohn's Disease and ulcerative colitis	Organization of Teratology Information Specialists (nonprofit) at the University of California, San Diego	300	Mar-12	https://clinicaltrials.gov/ct2/show/NCT01797224

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
OTIS Pregnancy Outcomes and Asthma Medications in Pregnancy Study	Multiple Drugs	Asthma	Organization of Teratology Information Specialists (nonprofit) at the University of California, San Diego	Unknown	2009	http://grantome.com/grant/NIH/R18-HS018474-01 ; https://mothertobaby.org/ongoing-study/asthma/
Cancer and Pregnancy Registry	Multiple Drugs	Cancer	Cooper Medical School at Rowan University	Unknown	Unknown	http://www.cancerandpregnancy.com/treating-cancer-in-pregnant-women/
Antiretroviral Pregnancy Registry	Multiple Drugs	HIV/AIDS	ViiV Healthcare; collaborator/sponsor is INC Research, LLC and GlaxoSmithKline	roughly 18787 as of Jan 2017	1989 (inception); 2/1/1993 (all antiretroviral drugs)	https://clinicaltrials.gov/ct2/show/NCT01137981 and http://www.apregistry.com/forms/interim_report.pdf
National Transplantation Pregnancy Registry	Multiple Drugs including Nulojix (belatacept)	Transplants, anti-rejection Medicines, immunosuppressants (e.g., belatacept for renal transplant)	Gift of Life Donor Program; Gift of Life Institute	Over 2300	1991	https://www.transplantpregnancyregistry.org/about-us/

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
National Pregnancy Registry for Atypical Antipsychotics	Abilify (aripiprazole), Aristada (aripiprazole lauroxil), Clozaril (clozapine), Fanapt (iloperidone), Geodon (ziprasidone), Invega (paliperidone), Latuda (lurasidone), Risperdal (risperidone), Saphris (asenapine), Seroquel (quetiapine), Zyprexa (olanzapine)	Mental Health Disorders	Center for Women's Mental Health at Massachusetts General Hospital	800	Nov-08	https://clinicaltrials.gov/ct2/show/NCT01246765 and https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/atypicalantipsychotic/
T.A.P.P. (Take Action to Prevent Pregnancy)	Acitretin	Psoriasis	Teva Pharmaceuticals	Unknown	Unknown	https://www.tevagenerics.com/assets/base/acitretin/PDFs/Acitretin_TAPP_Booklet.pdf
National Pregnancy Registry for Psychostimulants	Adderall (Amphetamine), Concerta, Daytrana, (Methylphenidate), Desoxyn (Methamphetamine HCl), Dexedrine (Dextroamphetamine), Focalin (Dextroamphetamine), Metadate CD, Methylin (methylphenidate HCL), Provigil (modafinil), Ritalin (methylphenidate HCL), Vyvanse (lisdexamfetamine Dimesylate)	ADD/ADHD	Center for Women's Mental Health at Massachusetts General Hospital	Unknown	Unknown	https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
The Vaccines and Medications in Pregnancy Surveillance System/OTIS Pregnancy Studies	Afluria	Influenza vaccine	Collaboration between <u>American Academy of Allergy, Asthma & Immunology (AAAAI)</u> ; Organization of Teratology Information Specialists Research Center at the University of California-San Diego (OTIS); Slone Epidemiology Center at Boston University (SEC); Harvard Pregnancy Research Group	Unknown	VAMPSS in 2009	http://www.aaaai.org/about-aaaai/strategic-relationships/vampss
MPS-I Registry	Aldurazyme (laronidase)	MPS I, Mucopolysaccharidosis I; Hurler's Syndrome; Scheie's Syndrome; Hurler-Scheie Syndrome	Sanofi Genzyme Corporation	1500	Nov-03	https://clinicaltrials.gov/ct2/show/NCT00144794

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
National Pregnancy Registry for Antidepressants	Anafranil (clomipramine), Asendin (amoxapine), Brintellix (vortioxetine), Celexa (citalopram), Cymbalta (duloxetine), Desyrel (trazodone), Effexor (venlafaxine), Effexor XR (Venlafaxine Hydrochloride), Elavil (amitriptyline), Emsam (selegiline), Fetzima (levomilnacipran), Fluoxetine (Fluoxetine Hydrochloride), Forfivo (Bupropion Hydrochloride), Lexapro (escitalopram), Ludiomil (maprotiline), Luvox (fluvoxamine), Marplan (Isocarboxazid), Nardil (phenelzine), Norpramin (desipramine), Pamelor (nortriptyline), Parnate (tranylcypromine), Paxil (paroxetine), Pristiq (desvenlafaxine), Prozac (fluoxetine), Remeron (mirtazapine), Serzone (nefazodone), Sinequan (doxepin), Surmontil (trimipramine), Tofranil (imipramine), Viibryd (Vilazodone Hydrochloride), Vivactil (protriptyline), Wellbutrin (bupropion), Wellbutrin SR (bupropion Hydrochloride), Zoloft (sertraline)	Depression	Center for Women's Mental Health at Massachusetts General Hospital	Unknown	Unknown	https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
Benlysta Pregnancy Registry	Benlysta (belimumab)	Systemic Lupus Erythematosus (SLE)	GlaxoSmithKline; collaborator/sponsor or is INC Research, LLC	500	Nov-11	http://pregnancyregistry.gsk.com/belimumab.html
Bexsero Pregnancy Registry	Bexsero (Meningococcal Group B Vaccine)	Meningitis Vaccine	GlaxoSmithKline; collaborator/sponsor or is INC Research, LLC	50	Jan-16	http://pregnancyregistry.gsk.com/bexsero.html
Exenatide Pregnancy Registry	Bydureon, Byetta (exenatide)	Type 2 Diabetes	AstraZeneca	7	Terminated 2016	https://clinicaltrials.gov/ct2/show/NCT00579150
Mycophenolate Pregnancy Registry	Cellcept (mycophenolate), Myfortic (mycophenolate)	Immunosuppressive drug (renal transplant) (potentially also heart and liver transplants and autoimmune diseases from clinicaltrials.gov)	Genentech; collaborator/sponsor or is INC Research, LLC	500	Nov-12	https://clinicaltrials.gov/ct2/show/NCT01733082
Cymbalta Pregnancy Registry	Cymbalta (duloxetine HCl)	Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), Diabetic Peripheral Neuropathic Pain (DPNP), Fibromyalgia	Eli Lilly and Co.; collaborator/sponsor or is INC Research, LLC	484	Jul-09	https://clinicaltrials.gov/ct2/show/NCT01074151
Fabry Disease Registry	Fabrazyme (agalsidase beta)	Fabry Disease	Sanofi Genzyme	9000	Jul-01	https://clinicaltrials.gov/ct2/show/NCT00196742

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
The Gilenya Pregnancy Exposure Registry	Gilenya (fingolimod)	Multiple Sclerosis (MS)	Novartis Pharmaceuticals	500	Oct-11	https://clinicaltrials.gov/ct2/show/NCT01285479
MotHER Pregnancy Registry	Herceptin (Trastuzumab), Kadcyla (ado-trastuzumab emtansine), Perjeta (pertuzumab)	Breast Cancer	Genentech	100	Jan-09	https://clinicaltrials.gov/ct2/show/NCT00833963
Merck Pregnancy Registry Program	Janumet (sitagliptin phosphate plus metformin hydrochloride), Januvia (sitagliptin phosphate)	Type 2 Diabetes	Merck & Co., Inc.	Unknown	Unknown	http://www.merckpregnancyregistries.com/januvia.html
Merck Pregnancy Registry Program	Maxalt (rizatriptan)	Migraine Headaches	Merck & Co., Inc.	Unknown	Unknown	http://www.merckpregnancyregistries.com/maxalt.html
Global Lomitapide Pregnancy Exposure Registry	Juxtapid (lomitapide)	Homozygous Familial Hypercholesterolemia	Aegerion Pharmaceuticals, Inc.	30	Oct-14	https://clinicaltrials.gov/ct2/show/NCT02399839
Motherisk: Lamisil in Pregnancy	Lamisil	Toe and Nail Fungal Infections	The Hospital for Sick Children	Unknown	Unknown	http://www.motherisk.org/
Motherisk Pregnancy Registry Program	Meridia (sobutramine hydrochloride)	Weight Loss Management	The Hospital for Sick Children	Unknown	Unknown	http://www.motherisk.org/

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
Menactra vaccine Pregnancy Registry; Sanofi Pasteur Pregnancy Registry	Menactra (meningococcal polysaccharide diphtheria toxoid)	Vaccine - Meningococcal Disease	Sanofi Pasteur	Unknown	Unknown	http://www.sanofipasteurpregnancyregistry.com/?fa=menactra
Menveo Pregnancy Registry	Menveo (Meningococcal quadrivalent CRM-197 conjugate)	Meningitis Vaccine	GlaxoSmithKline	100	Sep-14	http://pregnancyregistry.gsk.com/menveo.html ; https://clinicaltrials.gov/ct2/show/NCT02223637
Pompe Disease Registry	Myozyme (alglucosidase alfa)	Pompe Disease (GAA deficiency)	Sanofi Genzyme	2000	Aug-04	https://clinicaltrials.gov/ct2/show/NCT00231400
MPS VI Clinical Surveillance Program (CSP)	Naglazyme	Maroteaux-Lamy Syndrome also known as Polydystrophic Dwarfism or Mucopolysaccharidosis VI	BioMarin Pharmaceutical	200	July-05	https://clinicaltrials.gov/ct2/show/NCT00214773?order=2
Nuvigil and Provigil Pregnancy Registry	Nuvigil (armodafinil) and Provigil (modafinil)	Excessive sleepiness associated with: Obstructive Sleep Apnea, Hypopnea Syndrome, Narcolepsy, Shift Work sleep disorder	<u>Teva</u> Pharmaceuticals; United BioSource Corporation	300	Jun-09	https://clinicaltrials.gov/ct2/show/NCT01792583

Registry Name	Medicine(s)	Medical Condition(s)	Organization/ Sponsor	Enrollment	Date established	Website
Amgen's Pregnancy Surveillance Program	Prolia (denosumab)	Osteoporosis	Amgen	Unknown	Unknown	https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125320s0051mg.pdf
Promacta Pregnancy Registry; GlaxoSmithKline Pregnancy Registry	Promacta (eltrombopag)	Thrombocytopenia (ITP)	GlaxoSmithKline	1	Mar-10	https://clinicaltrials.gov/ct2/show/NCT01064336
A Rollover Study to Provide Continued Treatment With Eltrombopag	Promacta (eltrombopag)	Thrombocytopenia (ITP)	Novartis Pharmaceuticals	100	Oct-13	https://www.gsk-clinicalstudyregister.com/study/113101#ps and https://clinicaltrials.gov/ct2/show/NCT01957176
Ribavirin Pregnancy Registry	Ribavirin	Hepatitis C	INC Research, LLC	600	Jan-04	https://clinicaltrials.gov/ct2/show/NCT00114712
Savella Pregnancy Registry	Savella	Fibromyalgia	INC Research, LLC	350	Nov-09	https://clinicaltrials.gov/ct2/show/NCT01026077
Vibativ Pregnancy Registry	Vibativ (telavancin)	Antibacterial for skin infection	Theravance Biopharma R & D, Inc.	300	Nov-09	https://clinicaltrials.gov/ct2/show/NCT01130324
EXPECT Xolair Pregnancy Registry	Xolair (omalizumab)	Asthma	Genentech	304	Oct-06	https://clinicaltrials.gov/ct2/show/NCT00373061
Boostrix pregnancy registry	Boostrix	Diphtheria/tetanus/pertussis vaccine	GlaxoSmithKline	800	Mar-14	http://pregnancyregistry.gsk.com/boostrix.html ; https://clinicaltrials.gov/ct2/show/NCT02096276

Registry Name	Medicine(s)	Medical Condition(s)	Organization/Sponsor	Enrollment	Date established	Website
Varilrix pregnancy registry	Varilrix	Varicella vaccine	GlaxoSmithKline	Unknown	Unknown	http://pregnancyregistry.gsk.com/Varilrix.html
Priorix pregnancy registry	Priorix	Measles, mumps, and rubella vaccine	GlaxoSmithKline	Unknown	Unknown	http://pregnancyregistry.gsk.com/Priorix.html
Seasonal influenza vaccine pregnancy registry	Multiple (Fluarix, Fluarix Quadrivalent, Flulaval, Flulaval Quadrivalent)	Seasonal influenza vaccine	GlaxoSmithKline	Unknown	Unknown	http://pregnancyregistry.gsk.com/seasonalInfluenzaVaccines.html
Biogen Multiple Sclerosis Pregnancy Exposure Registry	Tecfidera (dimethyl fumarate); Pegylated human interferon beta-1a, and Dalclizumab High Yield Process	Multiple Sclerosis	Biogen	750	Oct-13	https://clinicaltrials.gov/ct2/show/NCT01911767
Vaxchora Pregnancy Registry	Vaxchora	Cholera vaccine	PaxVax	Unknown	Unknown	https://www.paxvaxconnect.com/vaxchora-pregnancy-registry
EllaOne pregnancy registry	ellaOne (female emergency contraceptive)	Female contraceptive	HRA Pharma	Unknown	Unknown	http://www.hra-pregnancy-registry.com/en/
Flucelvax pregnancy registry	Flucelvax	Influenza vaccine	Seqirus	Unknown	Unknown	http://flu.seqirus.com/flucelvax/pregnancy-registry.html