



ConcePTION

'Building a pan-European ecosystem for generating, monitoring, and providing robust information on medication safety in pregnancy and breastfeeding'

On 1-April 2019 a landmark public private partnership called ConcePTION was awarded a 5-year grant by the Innovative Medicines Initiative (IMI2) to tackle many of the research gaps related to medicine used by pregnant and breastfeeding women.

The project unites an unprecedented 88 organizations from 22 countries, including the European Medicines Agency, drug manufacturers, academia, public health organizations, and teratology networks to innovate new solutions to a decades-long public health issue. With a shared vision that there is a societal obligation to radically and rapidly reduce uncertainty about the safety of medication use in pregnancy and breastfeeding, the ConcePTION team will work to create sustainable solutions to the problem. Through better use of existing health data from routine, daily practice together with enhanced methods to collect patient-reported data, and with new research capabilities to predict and measure maternal medication in breastmilk, the team hopes to close the information gap.

Pregnant and breastfeeding women have long been overlooked in the medical research community because there have been few avenues available for conducting research; the fear of legal liability has overshadowed the need for reliable information to benefit these women and their families. Nonetheless, up to 90% of women are exposed to a prescription medication at some point during their pregnancy. Women and their healthcare providers face difficult choices before, during, and after pregnancy, due to a widespread lack of information. Physicians help women to select the safest medication, but they seldom have robust evidence to allow them to make informed decisions.

Today, only about 5% of medications have adequate safety information on use in pregnant or breastfeeding women. Obtaining reliable safety information can take 20 or more years to collect after a medicine is on the market.

ConcePTION aims to profoundly change this paradigm by improving and unifying currently uncoordinated approaches to data collection, and through the re-use of existing and de-identified health data that is generated during the routine care of patients, this is also called 'Big Data'. These data can be systematically and securely analysed to provide useful information about the effects of medicines on pregnancy outcomes in real life. ConcePTION does this by forming a networked system bringing together the major data sources dispersed across Europe. ConcePTION researchers also aim to create new pathways and methods for understanding medication transfer to breastmilk by creating the first Europe-wide breast milk biobank for research purposes. The team will also develop new models that can predict medication transfer into human breastmilk.

ConcePTION will create a trusted biomedical ecosystem that can efficiently, systematically, and in an ethically responsible manner, generate reliable evidence-based information regarding the safety of medications used during pregnancy and breastfeeding. ConcePTION aims to provide that

information in a form that is usable by both healthcare providers and women to facilitate informed decision making.

ConcePTION is a 5-year, €28.6 million project supported by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union and the European pharmaceutical industry. The pharmaceutical industry contributes €13.3 million to the project through in-kind contributions, whereas the European Commission funds €15.3 million in cash. The consortium, comprising close to 200 researchers, is governed and managed by a balanced 50/50 split of public and private partners, and is jointly led by Novartis and the University Medical Center Utrecht.

The Management team comprises representatives from Novartis, UCB Biopharma and University Medical Center Utrecht. The Management Board (work package leaders) has representatives from: European Institute of Innovation through Health Data, GSK, Janssen Pharmaceutica, LAREB, Katholieke Universiteit Leuven, Novartis, Sanofi Aventis, Takeda, UCB Biopharma, University Medical Center Utrecht, University of KwaZulu-Natal, University of Ulster and Uppsala Universitet.

Additional partners by country: **AT:** BBMRI-MUG, Biobanking and BioMolecular Resources Research Infrastructure – ERIC **BE:** Bionotus, European Forum for Good Clinical Practice, Provinciaal Instituut voor Hygiene, The Synergist **CH:** Arcades Sage-Femme, Groupement des sages-femmes indépendantes vaudoises, Registre Vaudois des Malformations, Division Autonome de Genetique Medicale, Universite de Geneve, University Hospital Geneva, University Hospital Lausanne, Pharmacology service, Pharmacometry unit, University Hospital Lausanne, Service of Obstetrics **CZ:** Masaryk University **DE:** Leibniz Institute for Prevention Research and Epidemiology, Otto-von-Guericke University, Malformation Monitoring Centre Saxony-Anhalt Medical Faculty, Merck Kommanditgesellschaft auf Aktien, University of Leipzig, Universitätskinderklinik Mainz, **DK:** Ellegaard Göttingen Minipigs A/S, Hospital Lillebaelt, Novo Nordisk A/S, Odense Universitetshospital, University of Aarhus, University of Copenhagen **ES:** Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana, IDIAP Jordi Gol **FI:** Terveystieteiden tutkimuskeskus **FR:** Centre Hospitalier Universitaire de Toulouse, Institut National de la Santé Et de la Recherche Médicale, Registre des Malformations Congenitales de la Reunion, Universite de Bordeaux, Rennes University Hospital **HR:** Department of Neonatology **IE:** Klinicka bolnica Sestre milosrdnice **IL:** Klinika za dječje bolesti Zagreb, European Institute for Women's Health, Jerusalem (Ministry of Health), Teva Pharmaceutical Industries Ltd. **IT:** Agenzia regionale di Sanità, Alma Mater Studiorum - Università di Bologna, Consiglio Nazionale delle Ricerche – Institute of Clinical Physiology, Università degli Studi di Ferrara, University of Florence, University of Messina **MT:** Malta Congenital Anomalies Registry **NL:** Academisch Ziekenhuis Groningen, Elevate, European Network Teratology Information Services Foundation (ENTIS), Orcion, PHARMO Institute, Rijksinstituut voor Volksgezondheid en Milieu, Ttopstart **NO:** University I Oslo **PL:** Poznan University of Medical Science, Dept of Medical Genetics, Wroclaw Medical University **SE:** Karolinska Institutet, Stockholms Lans Landsting **SW:** University of Lund **TR:** Izmir Katip Celebi Universitesi **UK:** Covance Laboratories Ltd., Eli Lilly and Company Ltd., GlaxoSmithKline Research and Development Ltd., Health Service Executive, Dept of Public Health, St Finbarr's Hospital, Medicines and Healthcare products Regulatory Agency, Pfizer Ltd., Public Health England, St. George's Hospital Medical School, Swansea University, The Newcastle Upon Tyne Hospitals NHS Foundation Trust, The University of Manchester, University of Bath, University of Dundee, The European Medicines Agency **US:** AbbVie Inc, Bristol-Myers Squibb Company Corp.



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