

Covid-19 infectiON and medicineS In preGNancy



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on behalf of the the EU PE & PV Research Network



Contributing organizations

- ▶ University Medical Center Utrecht, Utrecht, the Netherlands (UMCU)
- ▶ UKOSS, NPEU, University of Oxford, ITOSS, Rome, Italy , NOSS, Nordic countries, Inserm, France
- ▶ Universiteit Utrecht, Utrecht, The Netherlands (UU)
- ▶ Agenzia Regionale di Sanita' Toscana Italy (ARS)
- ▶ Aarhus University (AUH)
- ▶ University Copenhagen, Denmark (UCPH)
- ▶ Leibniz-Institute for Prevention Research and Epidemiology – BIPS, Germany (BIPS)
- ▶ Hospital Sanitaria Vall d'Hebron, Spain (FICF)
- ▶ Foundation for the Promotion of Health and Biomedical Research of Valencian Region (FISABIO), Spain
- ▶ Karolinska Institute, Sweden (KI)
- ▶ RTI Health Solutions (RTI-HS), Barcelona, Spain; North Carolina and Massachusetts, USA
- ▶ University Oslo, Norwegian Institute of Public Health, Norway (UiO)
- ▶ Instituto Aragonés de Ciencias de la Salud, Zaragoza Spain (IACS)
- ▶ University Swansea, UK (USWANSEA)
- ▶ University Bordeaux (BPE)
- ▶ University Lausanne/Bern, (UniBern)
- ▶ University of Manchester, UK.(UMAN)

Many questions remain, 10 months into COVID-19

Is a pregnant woman at higher risk to get COVID-19?

Is a pregnant woman with COVID-19 at higher risk of severe disease?

Is there a chance for vertical transmission of SARS-Cov-2?

What is the impact of COVID-19 disease on pregnancy outcomes?

What is the impact of medicines to treat COVID-19 on pregnancy outcomes?



Aim

To guide evidence based decision-making for regulators about COVID-19 vaccine indications, vaccination policies, and treatment options for pregnant women.

Objectives

- Assess use of medicines for COVID-19 treatment in pregnant women and compare with non-COVID-19/non-pregnant women of same age
- Describe severity and clinical outcomes of COVID-19 disease in pregnant women and compare to non-pregnant women of reproductive age with COVID-19.
- To assess and compare pregnancy and neonatal outcomes in different treatment groups of pregnant women for COVID-19
- To establish collaborations with other global initiatives (ICMRA) and have sustainability

CONSIGN works with strong networks in pregnancy field



Innovative Medicines Initiative - funded project with 88 partners aiming to build an ecosystem in Europe for monitoring medicines safety in pregnancy and lactation
<https://www.imi-conception.eu>



Multinational collaboration of organisations conducting prospective population-based studies of serious illnesses in pregnancy and childbirth, doi: 10.1111/aogs.12316. Epub 2013 Dec 30.

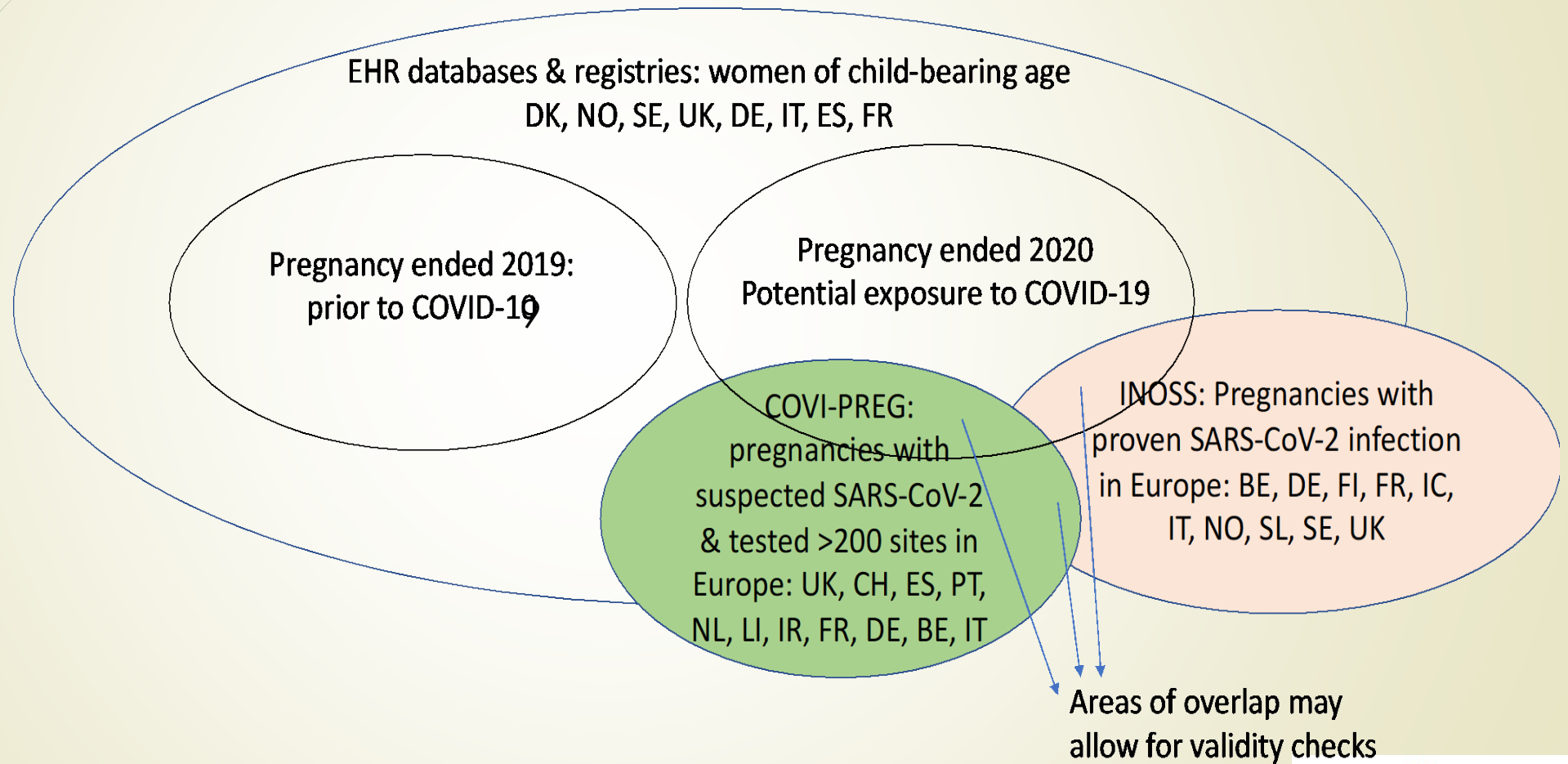


Multinational collaboration of organisations conducting prospective population-based studies of serious illnesses in pregnancy and childbirth

Approach

- ▶ **Primary data collection** (specific for purpose)
 - ▶ **INOSS**: ongoing standardized data collection at delivery for women with COVID-19 during pregnancy in INOSS countries
 - ▶ **COVI-PREG**: ongoing standardized data collection in health clinics at each visit for pregnant women with suspected COVID-19 in > 200 health facilities
 - ▶ Case control analyses
- ▶ **Secondary use of real world data collected in health care**
 - ▶ 9 Population based electronic health and medical birth registers in 8 countries, covering more than 1 million births per year
 - ▶ Women of childbearing age
 - ▶ Using ConcePTION tools and common data model

Overlaps and differences



Collaboration & sustainability

- ▶ **Collaboration with other international initiatives**
 - ▶ Sentinel
 - ▶ CNODES (Health Canada)
 - ▶ US-CDC
 - ▶ Other ICMRA available options
 - ▶ INOSS network outside of Europe
 - ▶ COVI-PREG sites outside of Europe
 - ▶
- ▶ **Sustainability of collaboration and pooling of data**
 - ▶ In Europe
 - ▶ Globally

Deliverables and timing

- ▶ Description of the network of electronic health care data sources, quality and background rates (January 2021)
- ▶ Study protocols for retrospective analyses (October 2020)
- ▶ Description how studies can be extended to other continents (December 2021)
- ▶ A report describing the prevalence of medicines and other treatments used in pregnant women with COVID-19, pregnant women without COVID-19 and non-pregnant women (July 2021)
- ▶ Report covering the results of the study for medicines effects on COVID-19 outcomes (July 2021)
- ▶ Report covering the results to assess medicines effects on pregnancy outcomes (July 2021)



Questions?