

Motherhood should not be a fight

Better safety information on medicines use during pregnancy and breastfeeding, with patients for patients

Welcome to the Patient Engagement Open Forum virtual session

Patient Engagement Open Forum is a series of virtual events (in 2020) where we will work together, in a multi-stakeholder context, **to turn patient engagement from an aspiration into reality.**

The Forum aims to provide **a holistic perspective** of patient engagement, the **landscape and actors**, and **foster collaboration** and **co-creation** while **breaking down fragmentation** that are often present in patient engagement work.



Let's work together to spread the word

#PEOF2020

@IMIConcePTION

@imi-paradigm

@eupatients

@PFMDwithPatient



Patient Engagement Open Forum Agenda in 2020

June 25th

PEOF2020 opening plenary (PARADIGM, PFMD and EUPATI)

Parallel sessions:

- Patient Engagement tools session #1 (consultation organised by PARADIGM)
- Patient engagement within MedTech (panel organised by EUPATI)
- Patient experience in regulatory processes (workshop organised by PFMD)

June 26th

Parallel sessions:

- How to engage patients in the early phases? (workshop organised by PFMD)
- Patient engagement in co-creating plain language summaries (workshop organised by PFMD)
- National Health Council Patient Engagement Fair-Market Value Calculator Toolbox (organised by NHC)

July 9th

Parallel sessions:

- Patient Engagement tools session #2 (consultation organised by PARADIGM)
- Flash presentations
 1. Sustainability roadmap for the patient engagement ecosystem
 2. Patient engagement agreements explained
 3. Patient engagement in medicines R&D in the CEE region
- Motherhood should not be a fight – better safety information on medicines use during pregnancy and breastfeeding, with patients for patients. (Workshop organised by IMI-Conception)

September 10th

Plenary session

- PARADIGM Patient Engagement Toolbox (webinar organised by PARADIGM)
- Patient Engagement Monitoring and Evaluation Framework (workshop organised by PARADIGM)

September 24th

Parallel sessions:

- How PE can foster access through improved affordability? (webinar organised by EUPATI)
- Patient engagement in clinical trial phase or/and in the regulatory submission phase (workshop organised by PFMD – to be confirmed at a later date)
- From diagnosis to treatment and beyond: personalised medicine – what's in it for patients and how to make it available to patients who could benefit from it? (workshop supported by PFMD)

October 15th

Parallel sessions:

- Patient Engagement and Quality by Design: Co-Developing an Implementation Roadmap for Clinical Trials (organised by CTTI)
- Good Lay Summary Practice, communicating trial results to the general public – How patient engagement can work (organised by EFPIA and EFGCP)

November 5th

THEME: Regulatory

November 23rd

Plenary session:

- PEOF2020 conclusion session

Practicalities



You will be **muted** when entering the webinar



You can provide feedback through participation in **polls and word clouds**



Sometimes we are interested in hearing your thoughts, you can enter them through the **chat function**



In the chat function you can choose to **submit your response** only to the panelists or to all attendees

Practicalities



When you want to say something, please use the raise hand icon



When you are given the word by the moderator, please unmute yourself and if you want to, turn your camera on.



This webinar will be recorded and the recording will be available on the Patient Engagement Open Forum website

Welcome!



Fergal
O'Shaughnessy



Miriam
Sturkenboom



Linda
Härmak



Roxana
Radu

ConcePTION overview

Prof. dr. Miriam Sturkenboom
on behalf of the ConcePTION consortium

www.imi-conception.eu

Slide set created by University Medical Center Utrecht

What is ConcePTION?

Public-private partnership

- Project funded by the EU Innovative Medicines Initiative (IMI)
- Co-led by Novartis and University Medical Center Utrecht

Duration

- April 1, 2019-March 31, 2024

Total funding

- 28 million Euro 15 million cash from EU, 13 million in-kind from EFPIA

<https://www.imi.europa.eu/projects-results/project-factsheets/conception>

Who is ConcePTION?

Management team

- Ida Niklson, Miriam Sturkenboom, Pieter Stolk, Theresa Rosario-Jansen

Managing Board (WP leads/observer)

- Helen Dolk, Anja Geldof, Laura Yates, David Lewis, Isabelle Huys, Michele Bouisset-Leonard, Mats Hansson, Theresa Rosario-Jansen, Agnes Kant, Stéphanie Tcherny-Lessenot, Dipak Kalra, Christine Allan, Miriam Sturkenboom, Marianne Cunningham, Pieter Stolk, Ida Niklson, Hildrun Sundseth

Participants

- > 200 persons from 88 organizations including the European Medicines Agency, drug manufacturers, academia, small medium enterprises, public health organizations, women's health and teratology networks

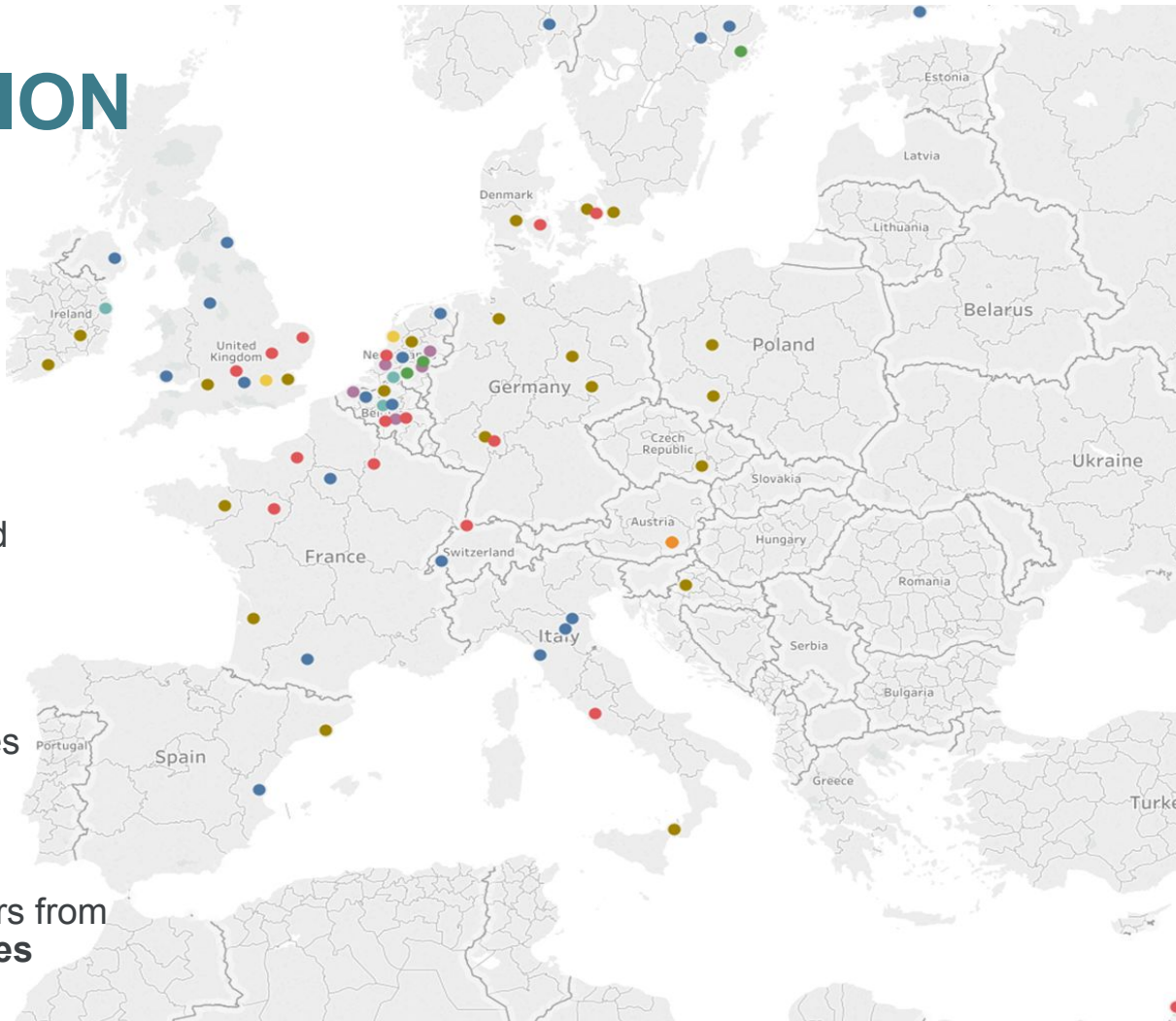
ConcePTION partners

 **51**
Partners

 **7**
Linked-third parties

 **28**
Third parties

 **>200**
Researchers from
22 countries



ConcePTION partners

Academic

UNIBO
UKZN
FERR
i~HD
UMCG
NIHW
ULAUS
KUL
UMAN
UNEW
UOSL
INSERM
CNR-IFC
SGUL
USWAN
CHUT
ULST
KI
UPSS
UMCU
FISABIO

Regulator

EMA
MHRA

EFPIA

NOVARTIS
GSK
UCB
Novo Nordisk
Merck
Janssen
Covance
Lilly
Ellegaard
Takeda
AbbVie
Pfizer
SANOFI
BMS
TEVA

NGO

ENTIS
EFGCP
EIWH

Blobank

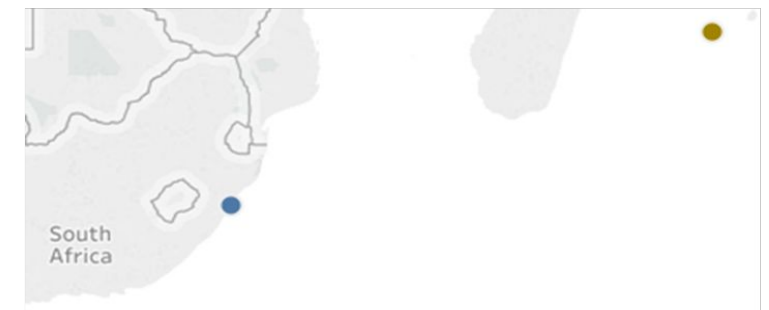
BBMRI-ERIC

Public health

RIVM
LAREB
SCC
SME
ttopstart
ORC
Synergist
Bionotus
Elevate

Third parties

- U-Bordeaux
- PHARMO Institute
- IDIAP Jordi Goll
- BIPS Institut
- UNIME
- MedUni Graz
- Masaryk University
- Uni-Leipzig
- UMed Wroc
- PIH
- KbcSm
- Hospital Lillebaelt
- University of Copenhagen
- CHU Rennes
- Registre des Malformations Congenitales de la Reunion
- Universitätskinderklinik Mainz
- MONZ, OVGU
- St Finbarr's Hospital
- HSE.ie
- Malta Congenital Anomalies Registry
- PUMS
- Lund University
- Registre Vaudois de Malformations
- Public Health England
- University of Bath
- Aarhus
- Dundee





Rationale

Why do we need ConcePTION?

A woman has the right to safe and effective use of medication based on scientific evidence, and she is taking a decision for two.

- Globally 200 million women get pregnant each year, 5 million in EU
- Many women have chronic illness or get ill
- Drug use is high

Proper evidence is largely lacking, incomplete or unknown, only 5% of labels have good information on risk in pregnancy

Fragmentation and inconsistencies regarding advice and knowledge, lack of sustainable infrastructure



ConcePTION aims to create a solution to change this

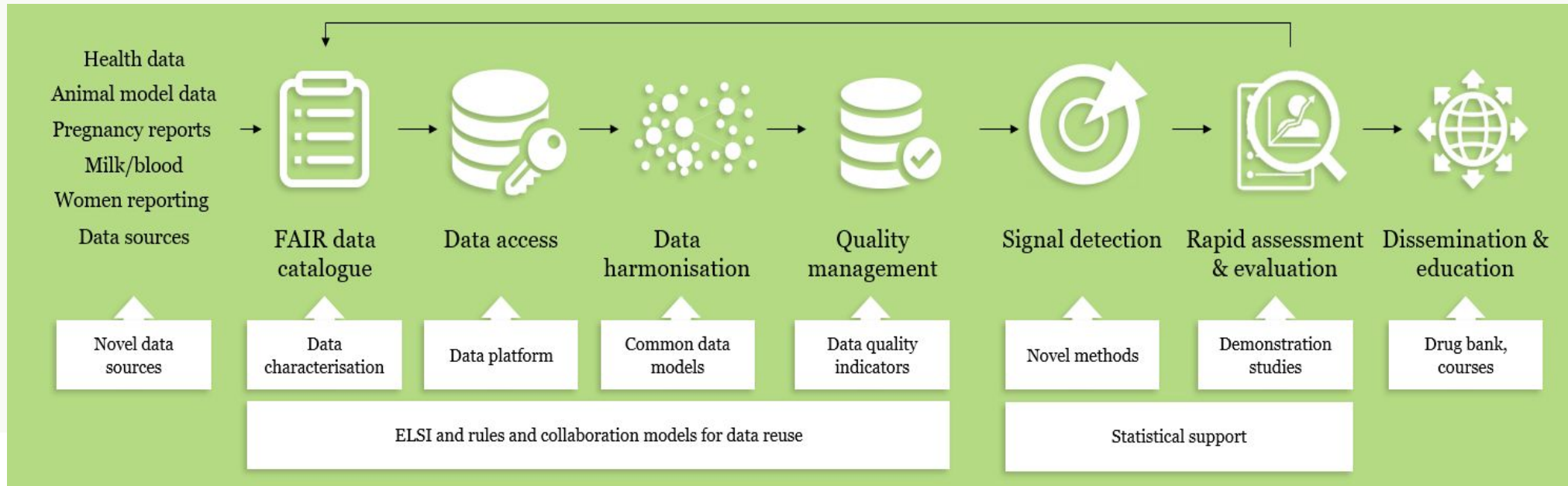
Mission of ConcePTION

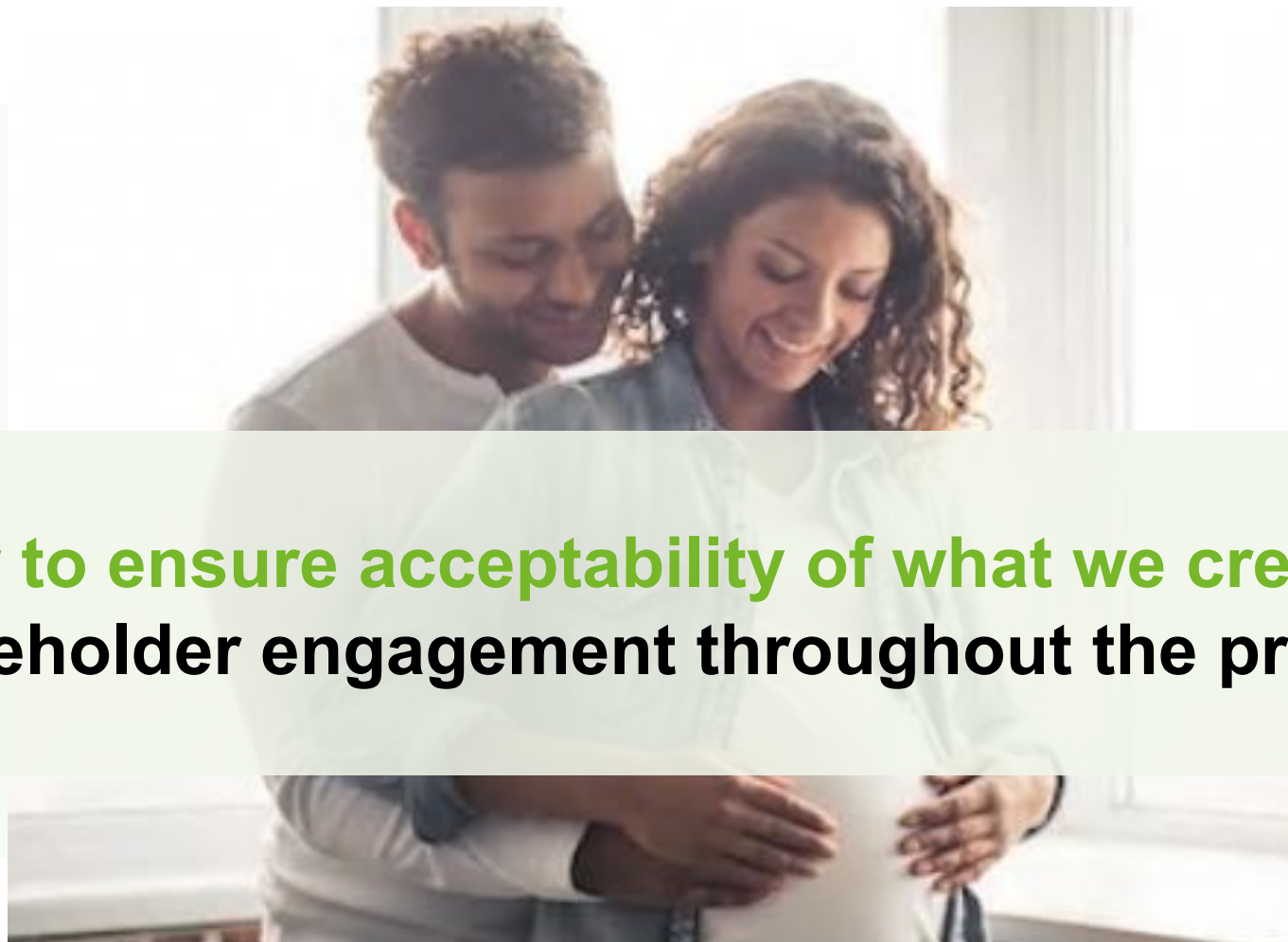
Building and testing a trustworthy pan-European ecosystem for **generating, monitoring, and providing robust and rapid real world evidence on medication safety in pregnancy and breastfeeding** in a collaborative and standardized manner to inform labels, women, families and health care professionals



ConcePTION evidence pipeline

Using available health data and new data to generate the evidence a woman needs in a robust and transparent manner





How to ensure acceptability of what we create?

Stakeholder engagement throughout the project

Questions?



Poll 1

Have you ever needed information about medicine use during pregnancy or breastfeeding?

- (a) Yes
- (b) No

Poll 2

Where did you look for this information first?

More than one answer possible

- Family/friends
- Medical doctor
- Midwife/nurse
- Pharmacy personnel
- Alternative medical shop personnel
- Internet (searching online, in social media or specific websites)
- Calling birth defect information service (not available in all countries)
- Print media (e.g magazines, newspapers)
- Information leaflet about medicine use during pregnancy or breastfeeding from your doctor's office
- Medicine packaging (medicine label or patient information leaflet)
- Other

Poll 3

Where did you find information online?

More than one answer possible

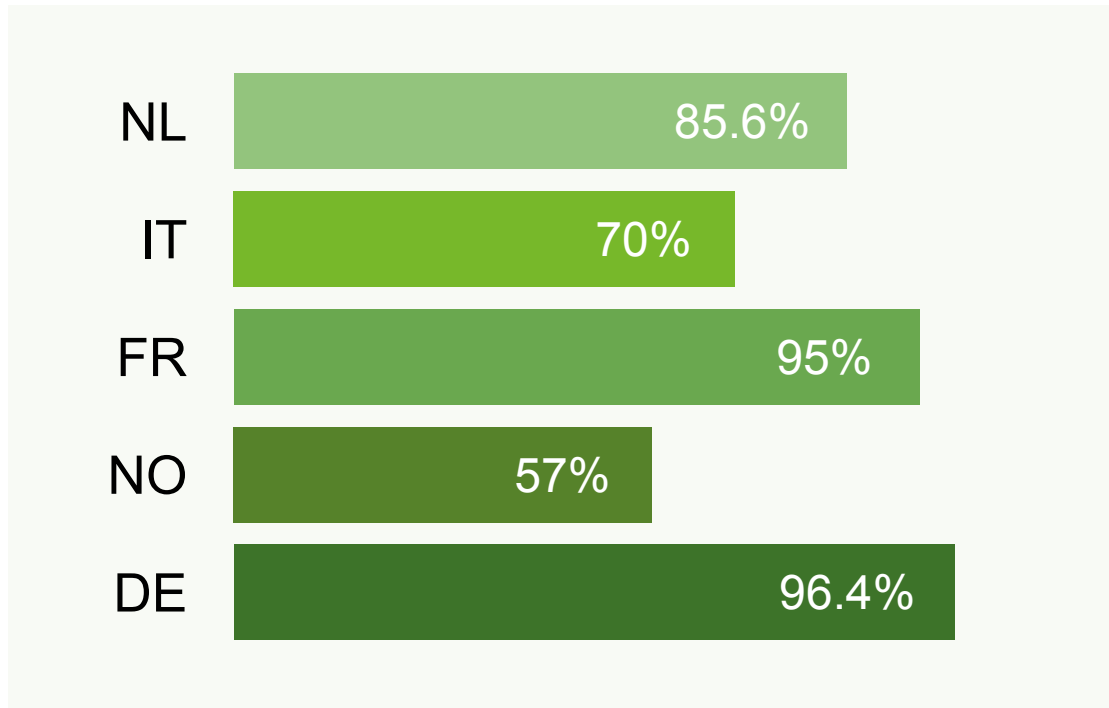
- Discussion forums
- Search engines
- Social media
- Online magazines
- Patient organization websites
- Scientific articles
- Patient information leaflet
- Birth defect information service (not available in all countries)
- National medical services
- Other

Word cloud

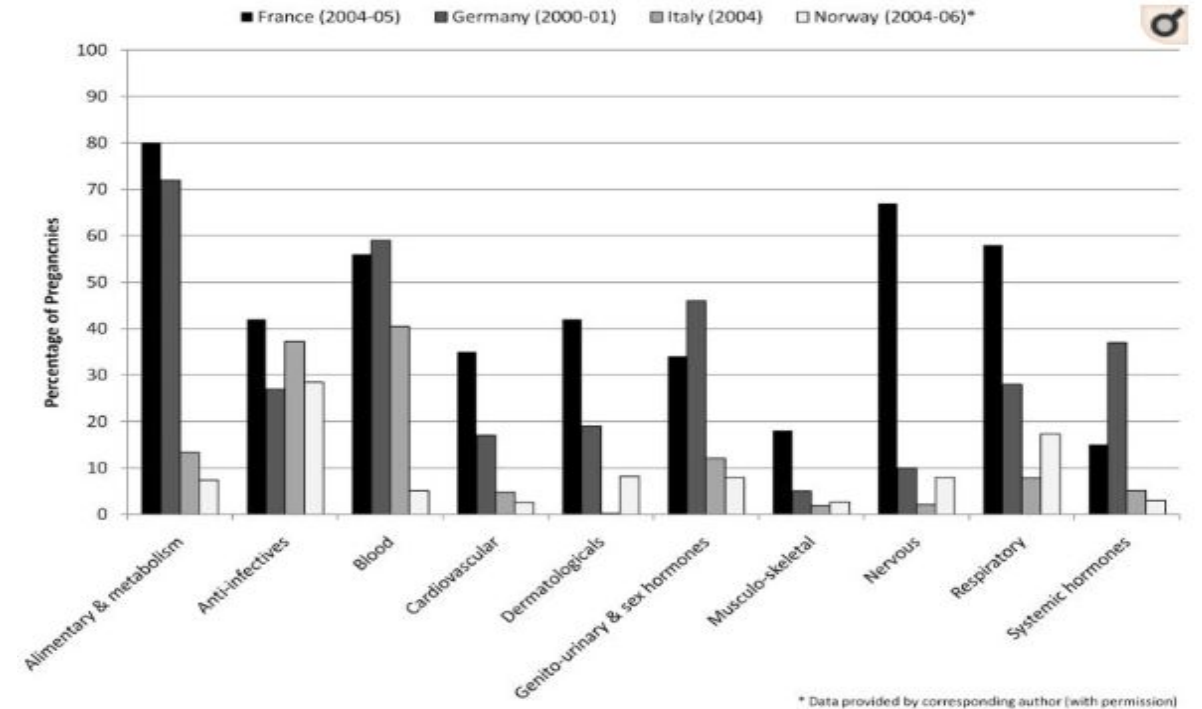
What makes you trust information about medicine use during pregnancy and breastfeeding that you find online?

Go to www.menti.com

A need for proper evidence: Drugs are frequently used during pregnancy



From Daw R 2011 doi: [10.1002/pds.2184](https://doi.org/10.1002/pds.2184)



doi.org/10.1016/j.ejogrb.2003.10.024. doi: 10.1007/s00228-009-0647-2. doi:10.1002/pds.2184;
Egen-Lappe V, Hasford J. Drug prescription in pregnancy: analysis of a large statutory sickness fund
population. Eur J Clin Pharmacol. 2004 Nov;60(9):659-66.; doi: 10.1111/j.1365-2125.2008.03102.x.

Why do we need a knowledgebank?

A woman has the right to safe and effective **use of medication** based on scientific evidence, and she is making a decision for two.

- Difficult to find high quality, trustworthy information
- Fragmentation and inconsistencies regarding knowledge and advice



Vision knowledgebank

Our vision is to create an independent, practical online search engine for both women and healthcare professionals. A platform that

- provides up-to-date information and advice validated by specialists,
- promotes safe & effective use of medicines for pregnant and breastfeeding mothers,
- empowers women to make informed decisions.

Try out knowledgebank



Open an internet browser and type in:

<https://pregnancy.orcicon.com/>

OR



click on the linked shared by us in the chat



Please move around the home page and click and read



Do not test the search function yet (this will come later)



After 5-7 minutes, please return to the Zoom so that we can discuss your feedback.

Discussion knowledgebank

What is your overall impression of the home page of the knowledgebank?

- Please write your impression in the chat.
-
- In the chat function you can choose to submit your response only to the panelists or to all attendees

Discussion knowledgebank

In-focus section

Do you have suggestions for topics which you would like to see here?

In Focus



COVID-19 and pregnancy

Pregnant women are not currently believed to be more at risk of contracting COVID-19...

[Read more >](#)

28 June



WHO recommends dolutegravir as preferred HIV treatment option in all populations

Based on new evidence assessing benefits and risks, the WHO recommends...

[Read more >](#)



Pain medication during pregnancy

Pain in pregnancy is common. There are no specific guidelines on the treatment...

[Read more >](#)



Ondansetron use during pregnancy

Ondansetron is a medicine used for the treatment of vomiting and nausea...

[Read more >](#)

Discussion knowledgebank

What do you think about adding information about maternal disease?
What kind of information would you expect to find?

Maternal medical conditions

RHEUMATOID ARTHRITIS

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a kind of arthritis that mainly affects your joints. It is an autoimmune condition...

[Read more >](#)

NAUSEA AND VOMITING

Nausea and Vomiting of Pregnancy (NVP)

NVP or morning sickness is the most common medical condition in pregnancy...

[Read more >](#)

DIABETES

Diabetes and Gestational Diabetes

Diabetes is a medical condition in which the body either does not make enough insulin...

[Read more >](#)

DEPRESSION

Depression

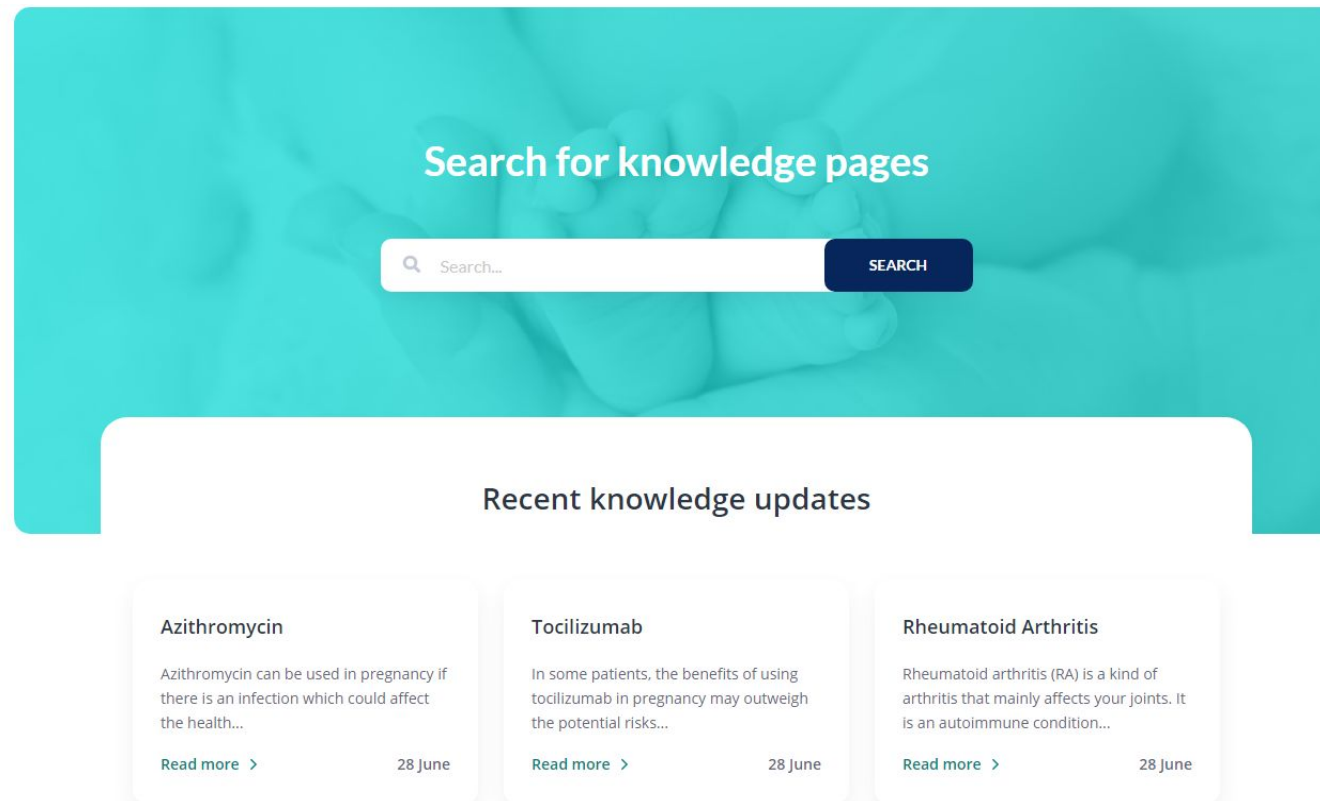
Depression is a serious medical illness. It can change how someone feels, thinks and acts. The most common symptoms..

[Read more >](#)

[VIEW ALL](#)

Discussion knowledgebank

Use the chat functions
to let us know what
search terms would
you use?



The screenshot shows a web interface for the Discussion Knowledgebank. At the top, there is a teal header with the text "Search for knowledge pages". Below this is a search bar with a magnifying glass icon, a placeholder text "Search...", and a dark blue button labeled "SEARCH". Underneath the search bar is a white box titled "Recent knowledge updates". This box contains three cards, each representing a knowledge update. Each card has a title, a brief description, and a "Read more" link with a right-pointing arrow. The date "28 June" is displayed at the bottom right of each card.

Knowledge Update	Date
Azithromycin Azithromycin can be used in pregnancy if there is an infection which could affect the health...	28 June
Tocilizumab In some patients, the benefits of using tocilizumab in pregnancy may outweigh the potential risks...	28 June
Rheumatoid Arthritis Rheumatoid arthritis (RA) is a kind of arthritis that mainly affects your joints. It is an autoimmune condition...	28 June

Discussion knowledgebank

What would make you
trust the information in the knowledge bank? Why?

- Please write your impression in the chat.
-
- In the chat function you can choose to submit your response only to the panelists or to all attendees

Try out time



Open an internet browser and type in:

<https://pregnancy.orcion.com/>

OR



click on the link shared by us in the chat



Please search for azithromycin



Read the texts for these drugs



After 10-15 minutes, please return to the Zoom so that we can discuss your feedback.

Poll 4 - Navigation

Is it clear where to go for pregnancy and breastfeeding information?

- (a) Yes
- (b) No

Could you find out how to access information in a different language?

- (a) Yes
- (b) No

Azithromycin

SEARCH

On this Page

[Pregnancy](#)[Breastfeeding](#)

Pregnancy

[Choose translation: Dutch | More](#)

Azithromycin can be used in pregnancy if there is an infection which could affect the health of the mother or the baby. There is quite a lot of information about azithromycin use during pregnancy. Most studies have not described any unwanted effects on the baby. Single studies have indicated small increased risks of miscarriage and birth defects. However, these findings are possibly due to the way the research studies were done. Other studies have not found the same risks.

Key message

Summary paragraph

Details

Maternal infection during pregnancy can be hazardous to both the mother and the unborn fetus. Adequate treatment of maternal infections which arise during pregnancy is therefore essential. The choice of antibiotic in pregnancy should generally be guided by local prescribing guidelines and the results of culture and sensitivity tests.

Detailed information

[Show more](#)

References

[Show](#)

References

Poll 5 - Content

What information did you find most valuable?

- (a) The opening sentence containing the key message
- (b) The summary paragraph
- (c) The 'Details' section
- (d) All of the information included in the summary paragraph and the 'Details' section?

Would you read the details section?

- (a) Yes
- (b) No
- (c) I'm not sure

Poll 6

The summary paragraph was:

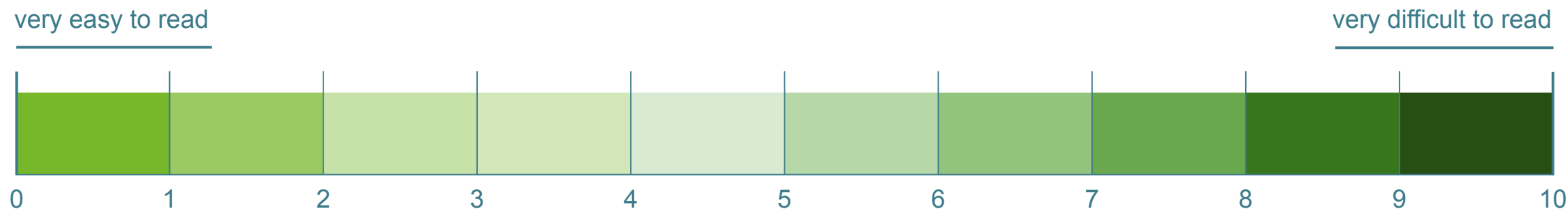
- (a) Too Much
- (b) Too Little
- (c) Just right

The amount of the information in the summary was:

- (a) Too Much
- (b) Too Little
- (c) Just right

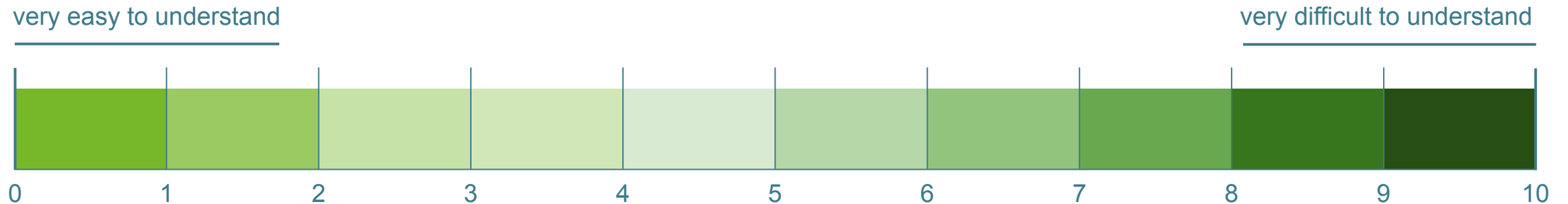
Poll 7 - Content

On a scale of 1 to 10, please rate the **readability** of the summary paragraph; with 1 being very easy to read and 10 being very difficult to read.



Poll 8 - Content

On a scale of 1 to 10, please rate your **understanding** of the summary paragraph;
with 1 being very clear and easy to understand and 10 being very difficult to understand.



Poll 9 - Action

What action does the information prompt

- (a) I would take this medicine if I needed it
- (b) I would not take this medicine even if I needed it
- (c) I would discuss it further with a healthcare professional before making a decision.

Poll 10 - Usefulness

Do you think the knowledge bank will be valuable to women who are pregnant?

- (a) Yes
- (b) No
- (c) I am unsure

Would you recommend the knowledge bank to others?

- (a) Yes
- (b) No
- (c) I am not sure

Word cloud 2

Tell us what liked about the knowledge bank?

Go to www.menti.com

For discussion

What suggestions do you have to improve the knowledge bank?

- Please write your suggestions in the chat.
-
- In the chat function you can choose to submit your response only to the panelists or to all attendees

Poll 11: Which phrases do you prefer?

1. (a) Mother (b) Pregnant woman
2. (a) Infant (b) Baby (c) Fetus/newborn
3. (a) Medication (b) Medicine (c) Drug
4. (a) Breastfeeding (b) Lactation
5. (a) Malformation (b) Birth defect
6. (a) Chance of (malformation) (b) Risk of (malformation)

Knowledge bank branding elements

Name & Tagline

Poll 12

Names:

1. MedicinesFor2
2. Preg-Med
3. Medicines for Mothers
4. Mother Aware of Medicine (MAM)
5. InForMother
6. InForMed
7. MUMS – Mothers Using Medicines Safely

Poll 13

Taglines:

1. Medicines you should know about during and after pregnancy
2. Make informed decisions about your medicines during pregnancy and breastfeeding
3. Trusted data for two
4. Trusted information for a positive motherhood experience
5. Know about safety of medicine during pregnancy and breastfeeding

Knowledge bank branding elements

Logo elements: iconography & colour

Poll 14
Logos:

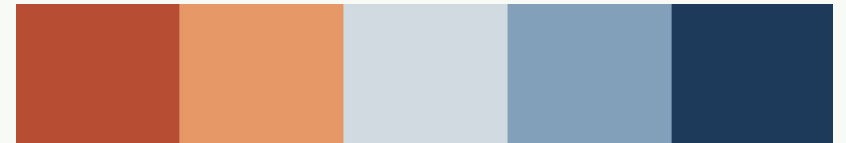


Poll 15
Colour palettes:

(1)



(2)



(3)



Wrap up and thank you

Please fill in the [survey](#) that will be sent to you tomorrow!

If you have any questions or feedback, please contact us at:

l.harmark@lareb.nl