



Updates ConcePTION* project WP5

MUMS Knowledgebank E-learning

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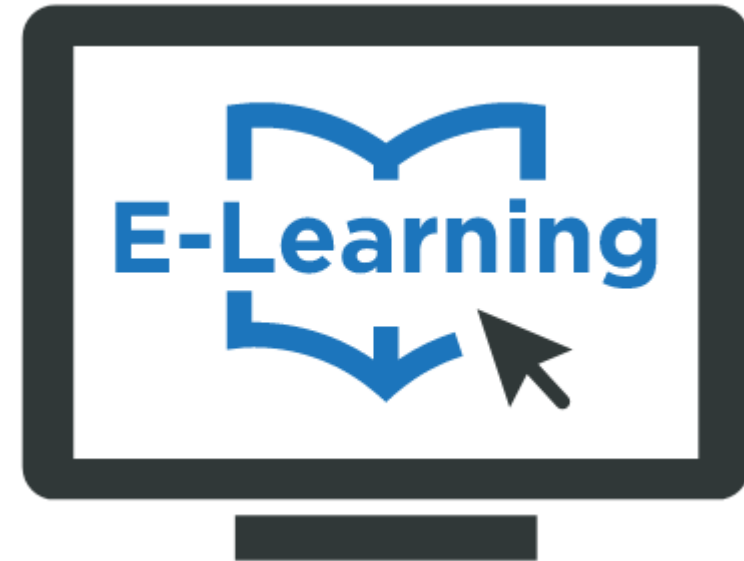
**Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now*

Anticipated outputs from ConcePTION

MUMS.eu Knowledge Bank



Health Professionals E-learning package



Underpinned by model of sustainability



MUMS.eu Knowledge Bank

- A freely accessible online information source with information about the safety of drugs during pregnancy and breastfeeding
- Each information page has a lay language summary and section with more detailed information
- Translation into local language is available



A change of direction for the KB

- The operating procedure (SOP) was developed for how the information pages would be produced and updated
- A very robust method for producing information pages was set, that could be considered as a gold standard for the provision of teratology information
- However, as the project progressed, it became clear that the **suggested costs were unlikely to be feasible or sustainable**, due to a large amount of person hours needed to produce KB pages



A change of direction for the KB

- A more sustainable, efficient and quicker procedure was developed
- Focus on giving trustworthy information about medicine use during pregnancy
- Link to website concerning breastfeeding (LactMed and/or Elactantia)
- Use of existing (freely available) evidence based websites instead of reinventing the wheel. When needed recent literature is added.
- Pages will be discussed by a review board existing of Entis members
- Provide a unified ENTIS opinion on the safety data
- The pages are translated into as many languages as possible





New writing process

1. The project identifies the priority medicines to include.
2. An assigned writer from the KB page writing group identifies the most up-to-date sources from across the TIS centres and other trustworthy publicly available sources.
3. The writer produces a first draft of the quick take and bullet point summary and circulates to the whole writing group for comments
4. Comments are considered and the KB summaries are altered and finalised
5. The KB page is approved for publication and circulated for translation
6. The KB summaries are published on the KB website with a link to the used sources.





**This way more pages can be created for
the KB and more people can be reached
(through the translations)**



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Search for information pages

loratadine

SEARCH

Recent knowledge updates

Omeprazole / esomeprazole

(Es)omeprazole can be used in pregnancy. There is quite a lot of information about (es)omeprazole use during pregnancy. The available data do not indicate an increased risk of major birth defects o ...

Amoxicillin

Amoxicillin can be safely used to treat an infection during pregnancy. Amoxicillin is a type of antibiotic . Antibiotics are used to treat a wide range of bacterial infections and are used by many ...

Loratadine and Desloratadine

Loratadine and desloratadine can be used for treatment of allergies and allergic conditions in pregnancy.

Translation possible for entire website, not just pages about medicine

Front End

Possible Breastfeeding section will provide link to the LactMed or ELactantia

An additional detail section in bullet point format (language can be a bit more advanced than the simple summary but not too advanced), this section is to include statements about (order can be decided by the author):

- Risks of leaving the condition untreated
- What the available evidence shows about risks of adverse pregnancy outcomes
- Any additional comments which require communication

Omeprazole / esomeprazole

On this Page

Pregnancy

Pregnancy

(Es)omeprazole can be used in pregnancy. There is quite a lot of information about (es)omeprazole use during pregnancy. The available data do not indicate an increased risk of major birth defects or other unwanted effects on the pregnancy or baby.

Details

- (Es)Omeprazole is a medication used to treat heartburn, stomach ulcers, and acid reflux (also known as gastroesophageal reflux disease or GERD).
- It belongs to a group of medicines called proton pump inhibitors (PPIs) that reduce acid released by the stomach. Esomeprazole ...

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References

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References

Click here to see references

Tis Netherlands. Lareb, Moeders van Morgen. Penicillines bij infecties tijdens de zwangerschap. Feb 2023. [Accessed May 2023]. Available from:

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[id=137&pagina=1&zoekterm=penicilline&zwangerschap=true&borstvoeding=true&naam=Penicillines%20bij%20infecties%20tijdens%20de%20zwangerschap](https://www.lareb.nl/mvm-kennis-pagina?id=137&pagina=1&zoekterm=penicilline&zwangerschap=true&borstvoeding=true&naam=Penicillines%20bij%20infecties%20tijdens%20de%20zwangerschap)

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[sheets/amoxicillin-clavulanate/](https://mothertobaby.org/fact-sheets/amoxicillin-clavulanate/)

The Women's Pregnancy and Breastfeeding Medicine Guide. Australia.

Amoxicillin. Feb 2023.

Reference list shows data sources and link to websites.



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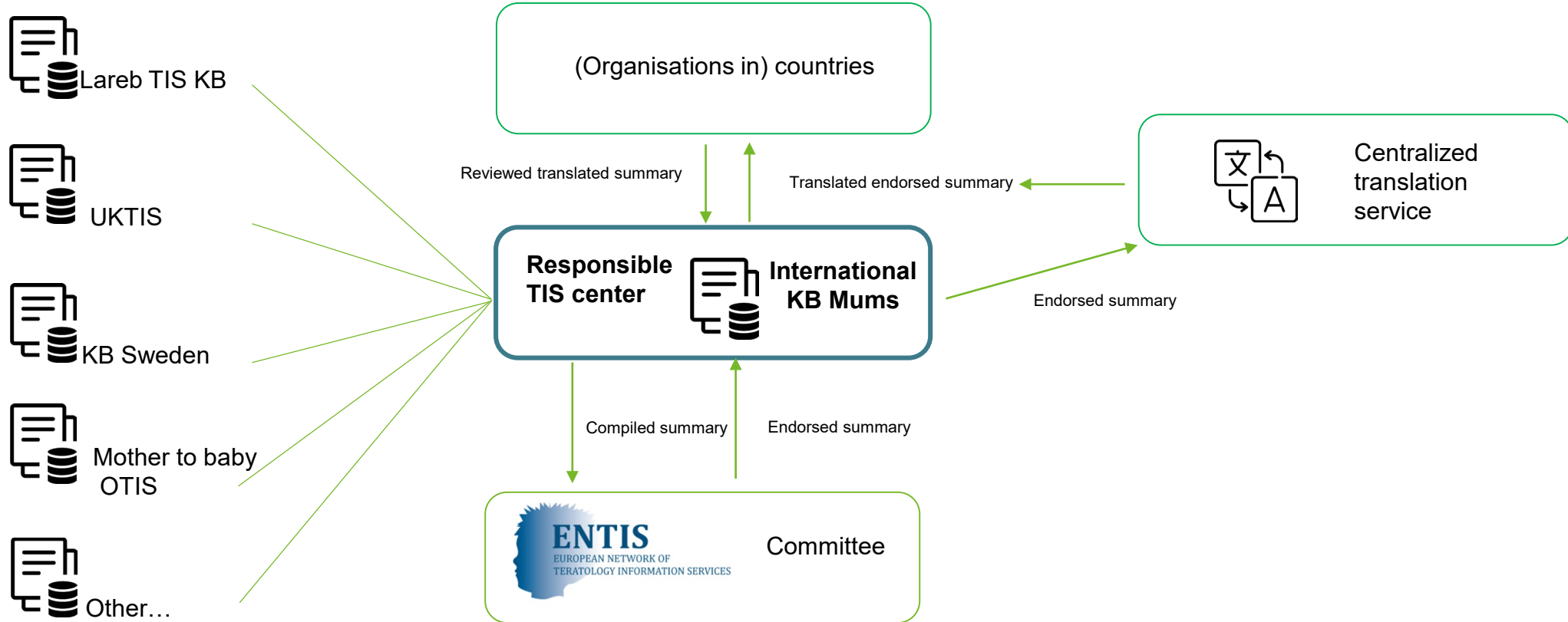
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WP 5 KB proposed operating model



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KB coordination model

- KB holder: one TIS center responsible for
 - Hosting MUMS knowledge bank
 - Coordinate IT updates, management and maintenance
 - Managing compilation of summaries of available information sources
 - consult internal resources and compile summaries
 - manage ENTIS committee endorsement of completed summaries
 - Managing updates of summaries
 - Define timelines for summaries to be updated
 - Managing translations of summaries and updates
 - Request translations to centralized translation provider
 - Manage local reviews of translations by TIS or local resources in countries without TIS



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ENTIS

- A committee of ENTIS will endorse the compiled summaries
- Regularly meetings for endorsement will be arranged online
- Members of the committee will be paid for participating per meeting
- TIS members can be contracted by the coordinating center for participating in the compiling process of the summaries





Translations

- The coordinating center will reach out for (organisations) in countries to be willing to take responsibility for reviewing translated compiled summaries
- This can be TIS centres, or other local organisations, governments
- The centralized translation process will be managed by the coordinating center



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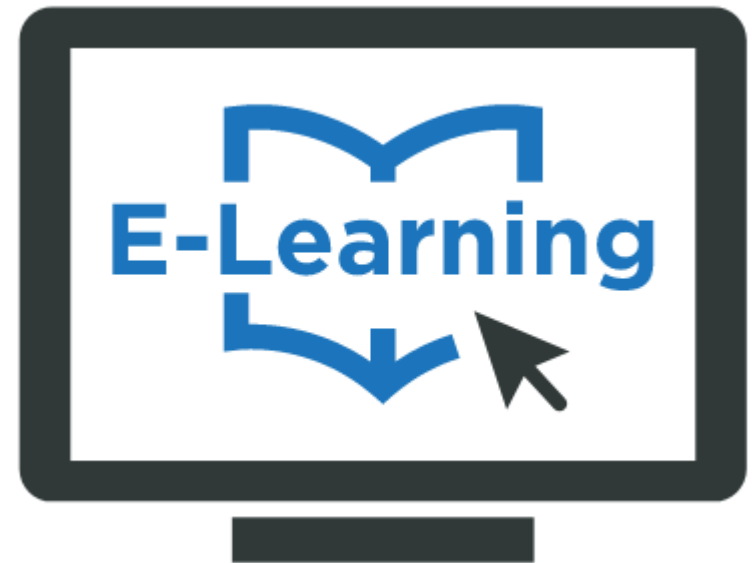
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- A comprehensive educational curriculum of 11 chapters is written by Entis members
- An online interactive self-study course was built; interactive framework with adaptive scenarios.
- There was an extensive pilot phase, during which feedback was collected to improve the course
- Certification of the course will be requested

Health Professionals E-learning package





Main menu



The course chapters
On this page you see the chapters of this course.





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The problem of “contraindicated” medicines

In the absence of a sufficient evidence base addressing the safety of medicines in pregnancy, many medicines are designated as “contraindicated”. Lack of access to information on the safety of medicines in pregnancy may result in pregnant women being reluctant to use medicines in pregnancy. This may lead to inadequate control of the disease and adverse pregnancy outcomes.

What are the risks that drugs are known to pose to pregnant women or their unborn babies?

What are the risks of untreated maternal conditions?

(Image based on an infographic from cdc.gov)



Birth defects



Pregnancy loss



Prematurity



Infant death



Developmental disabilities



Unknown outcomes

4B.1





Welcome to the demo course!

The development team is delighted that you are interested in this course. We believe that we can prevent birth defects, optimise pregnancy outcomes and minimise the risk of maternal death by ensuring the safe and effective use of medicines in pregnancy and breastfeeding.

demo link: <https://360.articulate.com/review/content/ca3f66a7-fccb-4b7c-8867-c1bf7484798b/review>



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ENTIS members participating in WP5

Rotunda Hospital (Irish Medicines in Pregnancy Service): Brian Cleary, Fergal O'Shaughnessy

UKTIS: Luke Richardson, Sally Stephens, Alison Oliver, Ken Hodson

Lareb: Benedikte Cuppers, Maartje Conijn, Anneke Passier, Lieke Vissers

TIS Zerifin: Maya Berlin, Mati Berkovitch

Region Stockholm (Janusmed): Ulrika Nörby

University of Oslo: Hedvig Nordeng



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