uk teratology information service

# ENTIS Annual Conference 2023

## Core data element recommendations for pregnancy pharmacovigilance studies using primary source data collection methods

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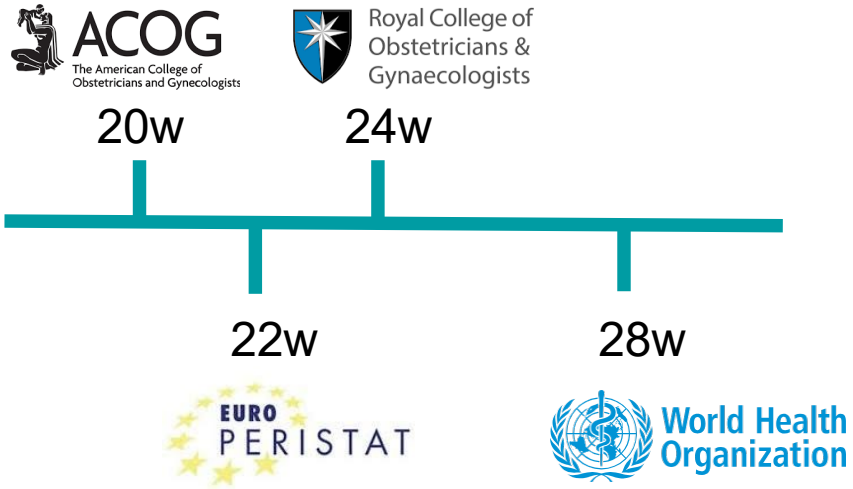
# IMI ConcePTION Core Data Elements

## Background

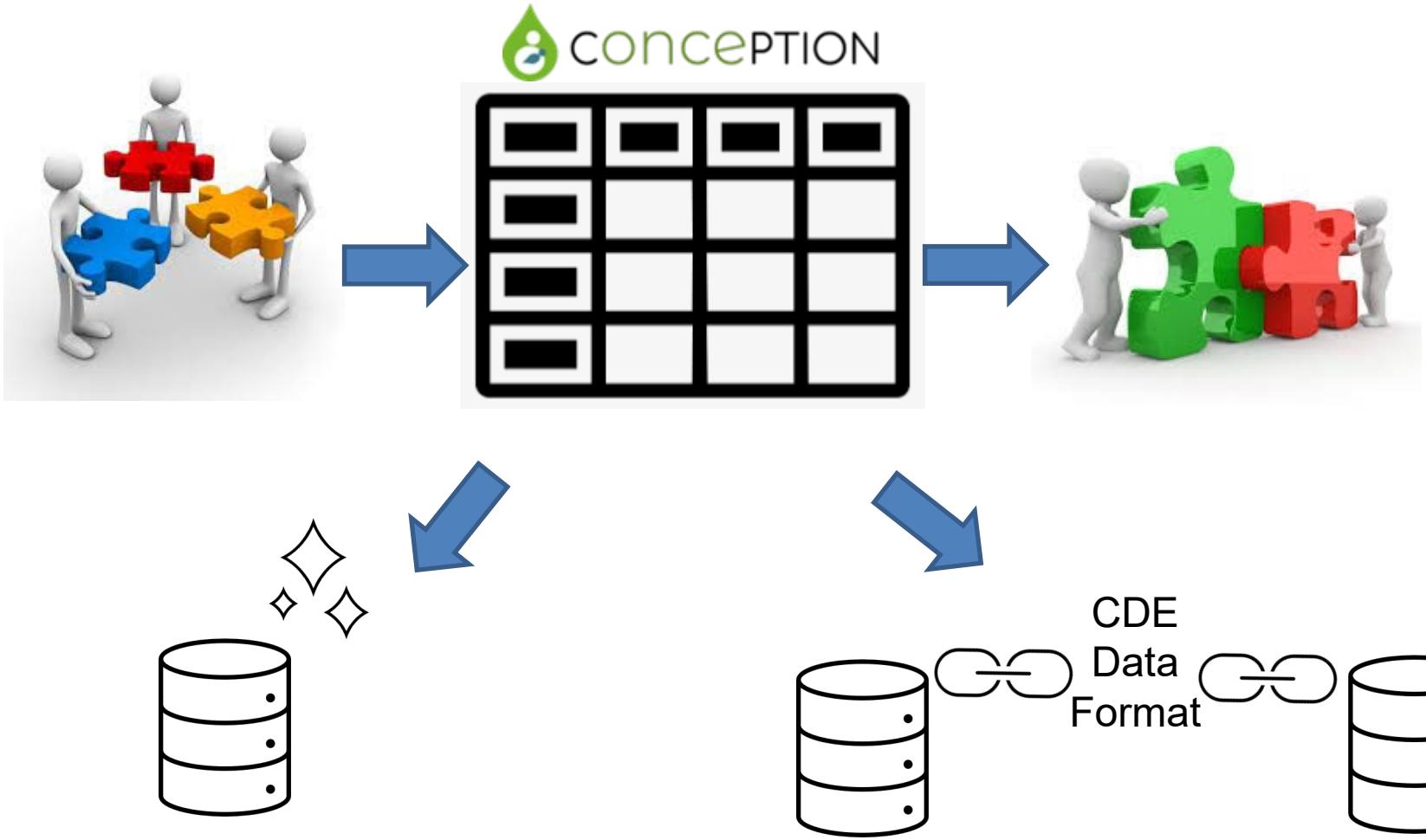




conceptION

*"develop a series of operational recommendations to optimise and standardise data collection techniques, analysis, and reporting in pregnancy pharmacovigilance (PregPV) research to improve data harmonisation and evidence synthesis capabilities"*

# IMI ConcePTION Core Data Elements

## Aims of the recommendations



# IMI ConcePTION Core Data Elements

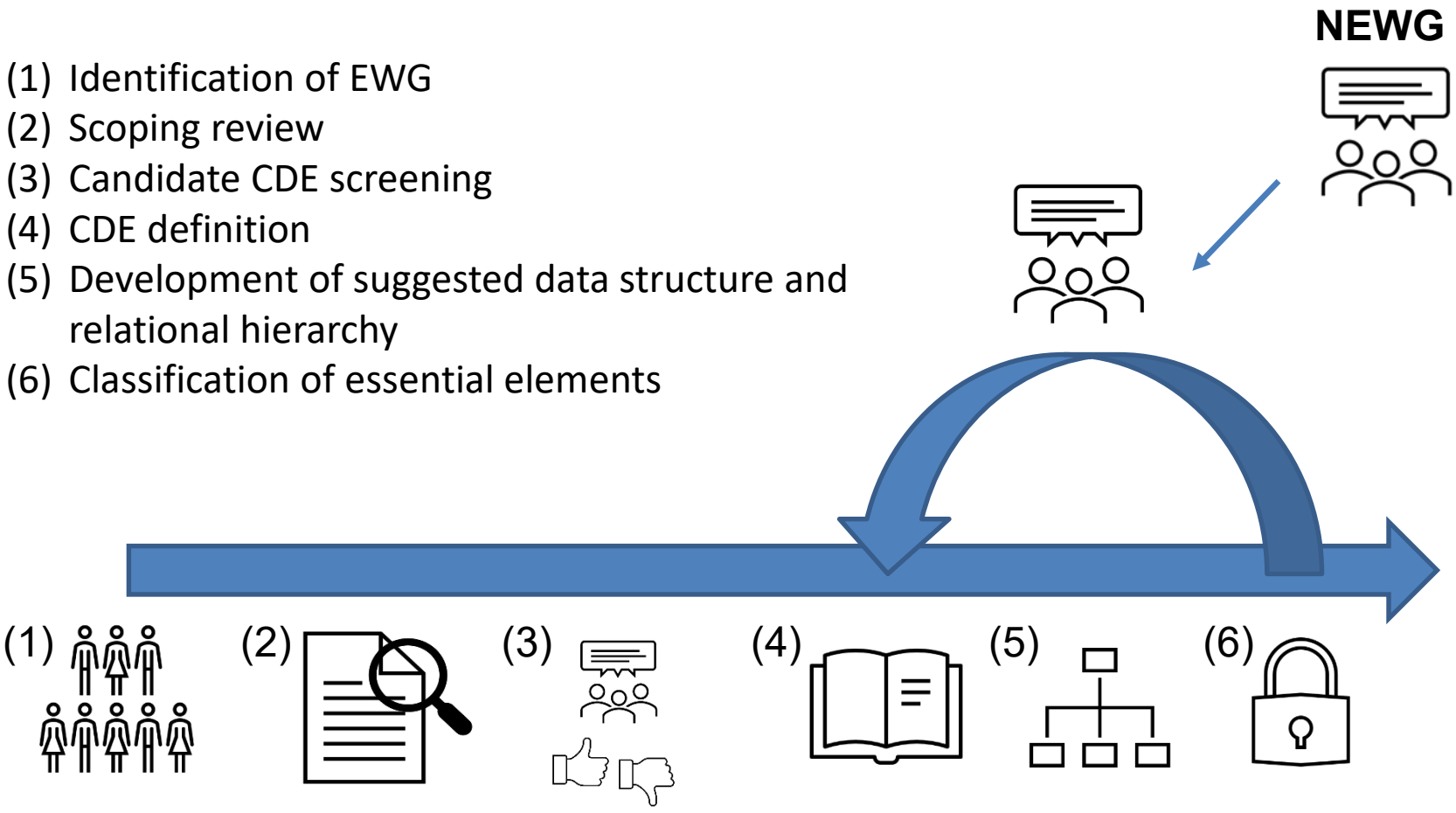
## Scope of the recommendations

| In scope | Out of scope |
|---|---|
| Maternal perinatal exposures | Paternal exposures |
| Pregnancy, fetal, neonatal and childhood outcomes | Breastfeeding exposures/outcomes |
| Co-variable risk factors | |

# IMI ConcePTION Core Data Elements

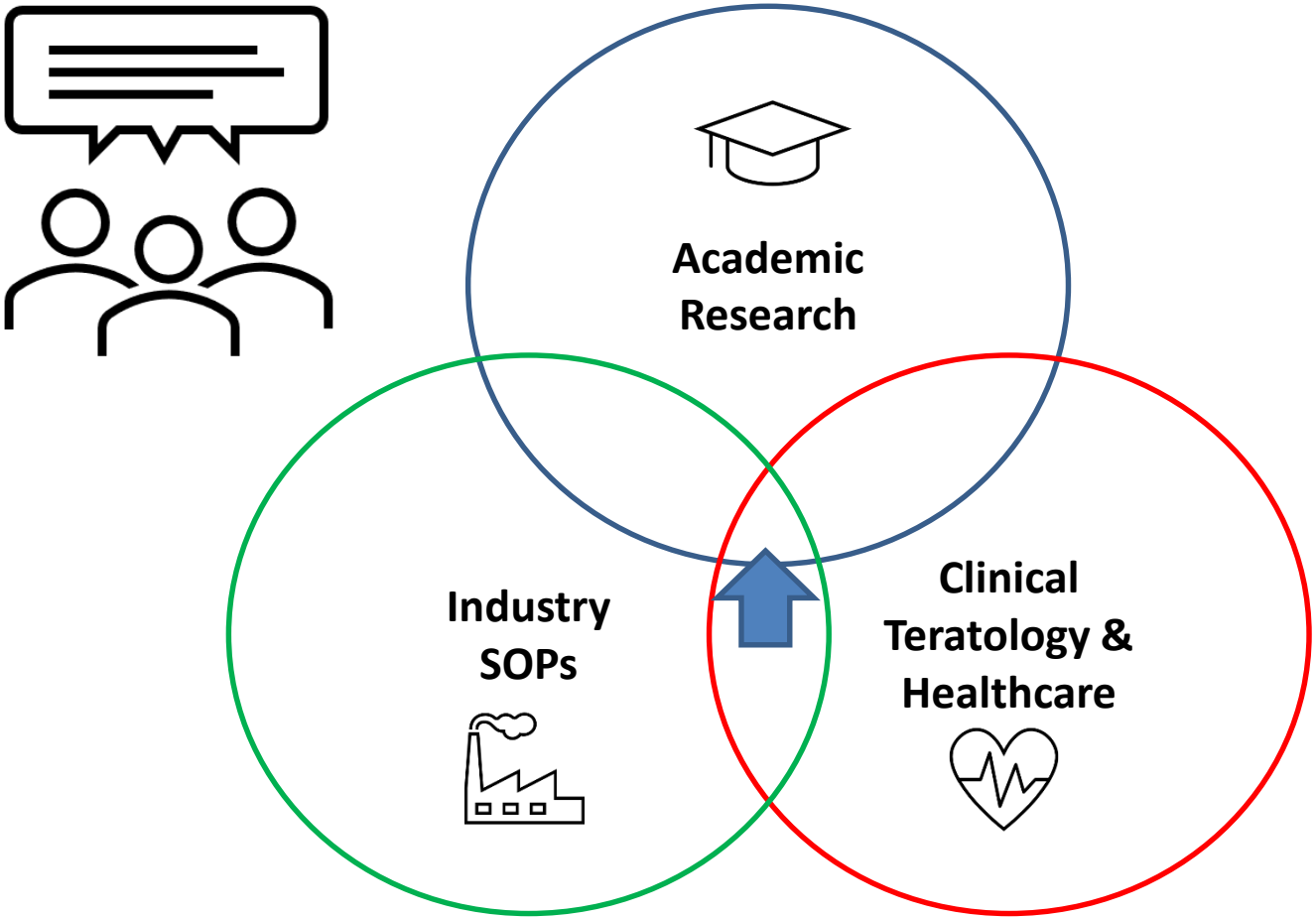
## Development of the CDE recommendations

(1) Identification of EWG
(2) Scoping review
(3) Candidate CDE screening
(4) CDE definition
(5) Development of suggested data structure and relational hierarchy
(6) Classification of essential elements



# IMI ConcePTION Core Data Elements

## Development of the CDE recommendations



# IMI ConcePTION Core Data Elements

## CDE recommendations framework overview

- Consensus opinion achieved after 20 rounds of review and debate
- Comprised of 98 data elements arranged in 14 tables
  - 63 essential for pregnancy/fetal/neonatal outcomes
  - 71 essential for longer-term childhood outcomes

# IMI ConcePTION Core Data Elements

## CDE recommendations framework overview

**Contents:**

# IMI ConcePTION Core Data Elements

## CDE recommendations framework overview

| CDE Item | Definition | Recommended data format and suggested values | Essential to collect when studying pregnancy and infant outcomes | Essential to collect when studying longer term childhood outcomes | Source | Purpose | Notes |
|---|---|---|---|---|---|---|---|
| Date of LMP | Date of the first day of the last menstrual period prior to conception | Date (dd/mm/yyyy) | Yes | Yes | Directly reported | Derivation (Pro-/retrospective reporting status)<br><br>Derivation (exposure timing)<br><br>Derivation (gestational age at pregnancy outcome) | This refers to the LMP associated with this pregnancy (not with earlier cycles).<br><br>LMP is derived as EDD-280 days (please note in early pregnancy, the EDD is derived from LMP, whereas in later pregnancy the EDD can be defined from ultrasound fetal crown-rump length measurements) or (where EDD is unknown) the date of end of pregnancy minus the gestational age at end of pregnancy (in days).<br><br>International variations exist with regards to updating the EDD (based on ultrasound fetal crown-rump length measurements) during prenatal care. In some locations, these updates may always be applied, whereas in others they may only be appliedd if the EDD is altered by >5 days. |
| Expected date of delivery (EDD) | Expected date of delivery | Date (dd/mm/yyyy) | Yes | Yes | Directly reported | Derivation (Pro-/retrospective reporting status)<br><br>Derivation (exposure timing)<br><br>Derivation (gestational age at pregnancy outcome) | The directly reported value may have been based on (e.g.) the date of LMP, results from ultra-sound examinations, the date of embryo transfer (assisted fertilisation).<br><br>Alternatively, it could be derived from entered dates of LMP based on 280 day gestation length (using the LMP date) or 266 day gestation length (using estimated date of conception from fetal ultrasound measurements). |

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## Controversial CDEs – Trimester definition

| | ACOG The American College of Obstetricians and Gynecologists | Royal College of Obstetricians & Gynaecologists |
|---|---|---|
| T1 | 0 to 96 days (LMP to 13+6 weeks) | 0 to 90 days (LMP to 12+6 weeks) |
| T2 | 97 to 195 days (14 to 27+6 weeks) | 91 to 188 days (13 to 26+6 weeks) |
| T3 | 196 days onwards (>28 weeks) | 189 days onwards (>27 weeks) |

In the future – Can we use a more optimised definition of exposure relevance?

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## Controversial CDEs – Prospective definition

| | **At the time of initial reporting:** |
|---|---|
| ***Simple definition*** | • Exposure occurring in pregnancy<br>• Pregnancy ongoing |
| ***EMA definition*** | • Exposure occurring in pregnancy<br>• Pregnancy ongoing<br>• No anomalies detected through prenatal screening |
| ***FDA definition*** | • Exposure occurring in pregnancy<br>• Pregnancy ongoing<br>• No prenatal screening performed |

# IMI ConcePTION Core Data Elements

## Published versions

Review > Drug Saf. 2023 May;46(5):479-491. doi: 10.1007/s40264-023-01291-7.
Epub 2023 Mar 28.

### Core Data Elements for Pregnancy Pharmacovigilance Studies Using Primary Source Data Collection Methods: Recommendations from the IMI ConcePTION Project

Jonathan L Richardson [# 1 2], Alan Moore [# 3], Rebecca L Bromley [4 5], Michael Stellfeld [6], Yvonne Geissbühler [7], Matthew Bluett-Duncan [4], Ursula Winterfeld [8], Guillaume Favre [8], Amalia Alexe [9], Alison M Oliver [10], Yrea R J van Rijt-Weetink [11], Kenneth K Hodson [10], Bita Rezaallah [12], Eugene P van Puijenbroek [# 11 13], David J Lewis [# 14 15], Laura M Yates [# 16 17]

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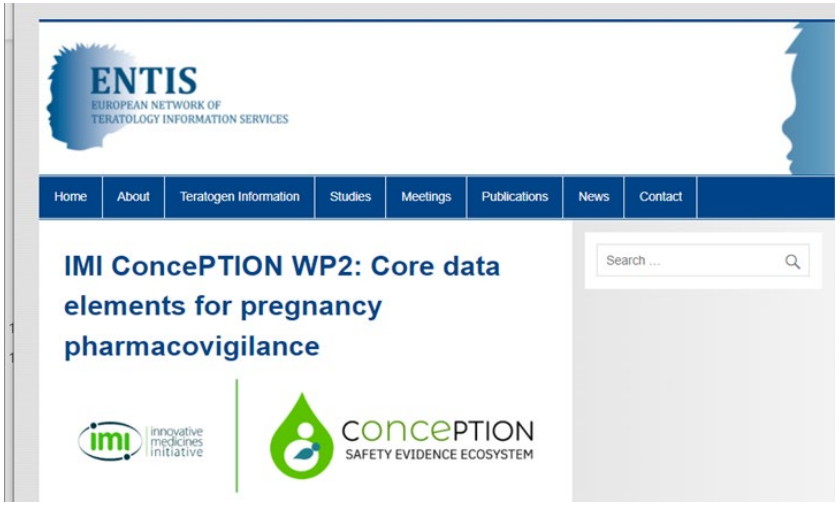


https://www.entis-org.eu/cde

# IMI ConcePTION Core Data Elements

## Limitations and future work

**Limitations**

- Recommendations represent a consensus agreement
- Disease severity/activity during pregnancy/post-partum not considered
- Exposure/disease specific adaptations likely needed

**Future work**

- Extensive promotion work needed
- Regular review and update
- Statistical analysis/reporting standards