Impact of data source diversity on the distribution of key variables in pregnancy cohorts based on the ConcePTION pregnancy algorithm leveraging a random forest imputation model

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on behalf of the Pregnancy Algorithm team

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Disclosure

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MS is coordinating a department that conducts studies for EMA and pharmaceutical companies (Pfizer, AstraZeneca, Janssen) using the ENCePP code of conduct.
MC works for Analysis Group that receives funds from Pharmaceutical Companies to conduct real world studies

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Background

ConcePTION Project

Aims to establish a trusted consortium that can efficiently, systematically, and in an ethically responsible manner, **generate and disseminate reliable evidence-based information regarding effects of medications used during pregnancy and breastfeeding** to women and their healthcare providers

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Background

ConcePTION Pregnancy Algorithm

Aims to identify the **most comprehensive list of pregnancies** occurring in the population of the participating data sources, incorporating all possible scenarios in a **transparent and common framework**

The algorithm is stored in a publicly accessible GitHub repository
Diagnosis code list used in the algorithm publicly available on Zenodo

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Aim of the study

To describe the impact of data diversity of 10 European data sources on the results from the ConcePTION Pregnancy Algorithm

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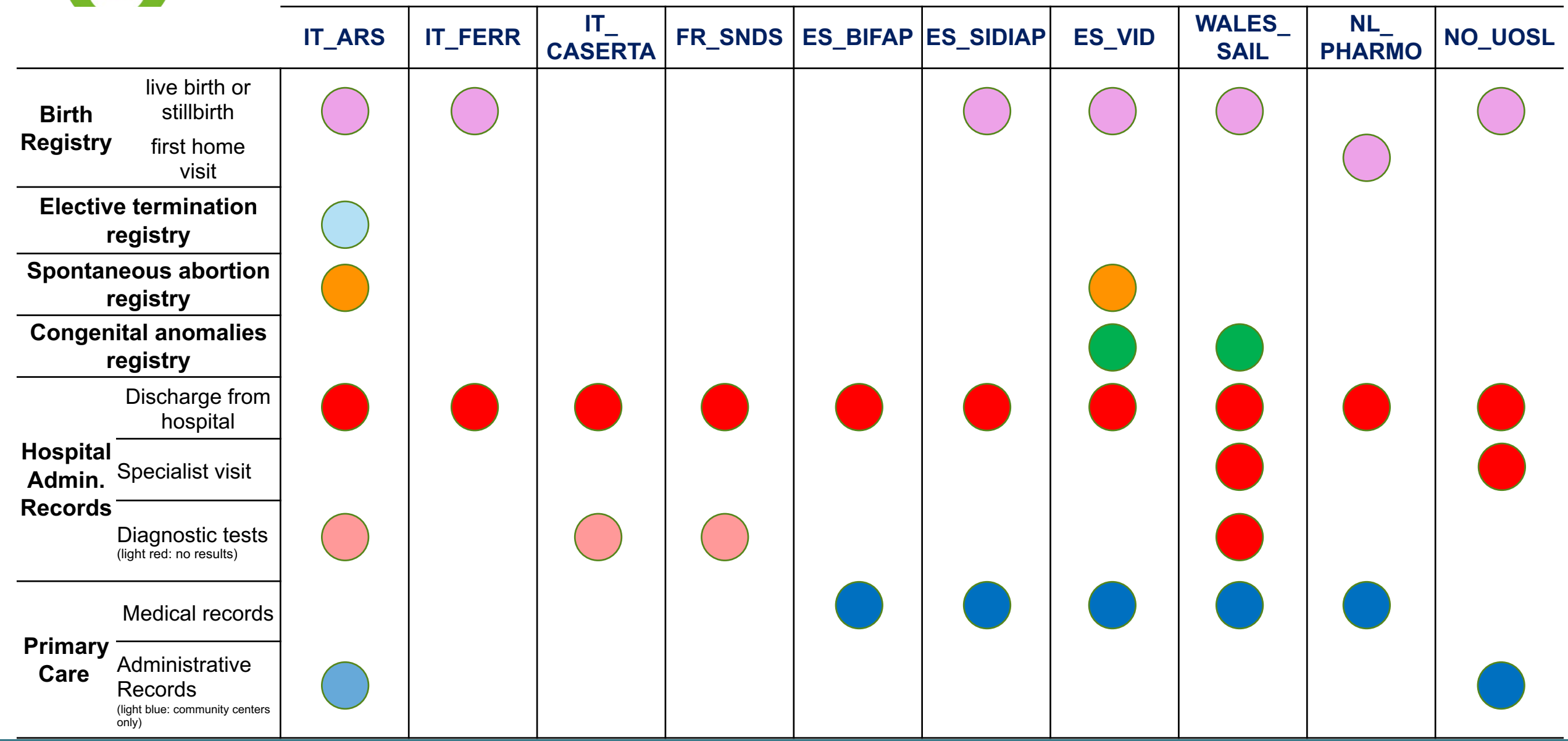
METHODS: Geographical distribution of data sources

METHODS: Diversity of data sources

analysis according to the DIVERSE framework (Gini R et al. 2024)



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METHODS: overall design of the meta-algorithm

1 Retrieval and labelling of records

(study period = 01/2015-12/2019)

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A

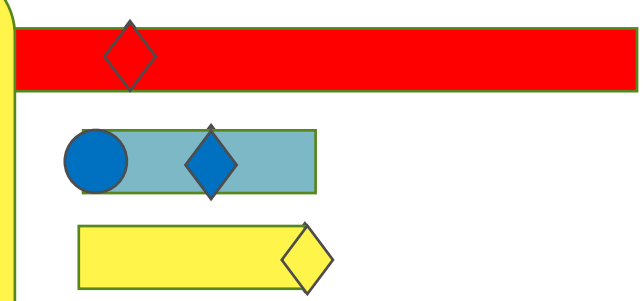
Some records imply that the pregnancy has ended on record date, and also carry information on gestational age at that date

Some records imply that the pregnancy is ongoing on record date, but do carry information on gestational age at that date

B

Some records do not carry any specific information neither on start nor on end date of pregnancy

Some records imply that the pregnancy has ended on record date, but don't carry explicit information on gestational age at that date



Time

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METHODS: overall design of the meta-algorithm

2 Exclusion criteria

1. The ‘person identifier’ was not recorded in the list of persons included in the data source;
2. The person was not in fertile age (12-55y) at the start of pregnancy;
3. Records whose record date was not included in the periods when the person was observed in the data source

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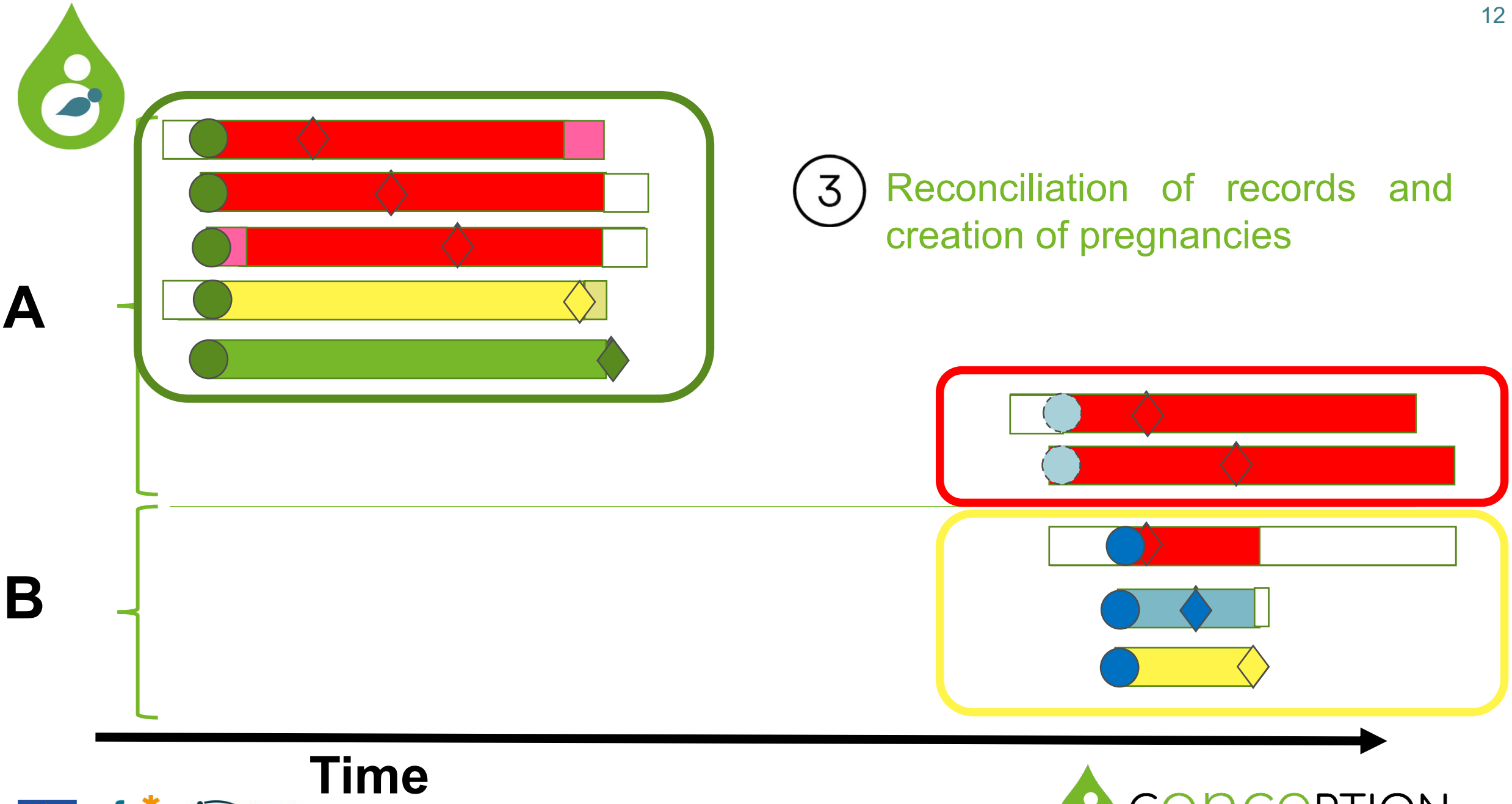

3 Reconciliation of records and creation of pregnancies

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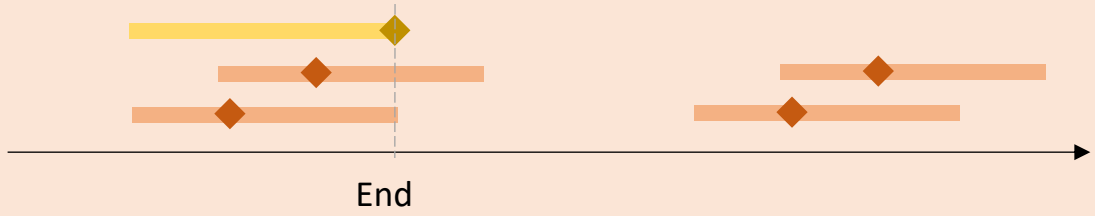
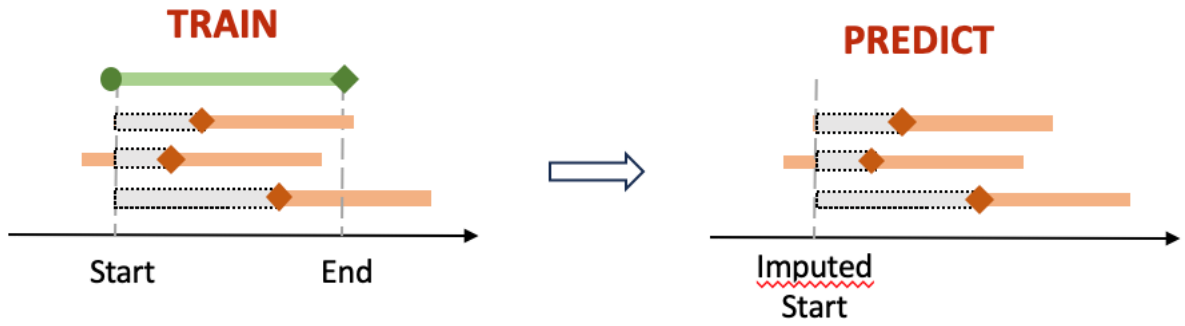
METHODS: overall design of the meta-algorithm

4 Predictive model for pregnancy start date

- In data sources with green records (such as the birth registries records)
- Based on a Random Forest model

We predict start of pregnancy for yellow and red records using green and blue records





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METHODS: overall design of the meta-algorithm

5 Output

- ✓ Final dataset of pregnancies
  - Main variables: start date, end date, type of pregnancy end
  - Other variables to track the choices made by the algorithm
- ✓ Descriptive markdown report
- ✓ Sample of pregnancies for manual verification of choices

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Types of pregnancy end in the ConcePTION Pregnancy Algorithm

LB	Live birth	the pregnancy ended in a live birth
SB	Stillbirth	fetal death before or during the delivery, after gestational week 22 or week 24 in UK
SA	Spontaneous abortion	pregnancy loss before 22 weeks' gestation (24 weeks in UK)
T	Elective termination	legal termination of pregnancy /medical abortion
ECT-MOL	Ectopic or molar pregnancy	the fertilized egg implants outside the uterus or there is evidence of abnormal product of conception
ONGOING	Pregnancy ongoing	the estimated date of end of pregnancy is after the date on which data are extracted
UNK	Unknown	the imputed or observed date of end of pregnancy is before the cutoff date of the data, therefore the pregnancy has surely ended, but the type of end could not be established
UNF	Unfavorable Unspecified	non-live birth pregnancy with observed end date, but outcome unspecified
LOSTFU	Lost to follow-up	the estimated date of end of pregnancy is after the end of the observation period (i.e. a continuous period of inclusion in the underlying population of the data source) of the pregnant person

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CONCLUSIONS

- ✓ **Creation of a meta-algorithm** that handle in a transparent manner data source diversity
- ✓ Tested on **10** diverse European data sources
- ✓ **Distribution of quality and types of pregnancy end** influenced by data diversity
- ✓ **Decision on which pregnancies are included in the study** should be based on the data source and on the research question, to minimize bias

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Thanks to all the research partners

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