

Harmonization working group: Update and future steps



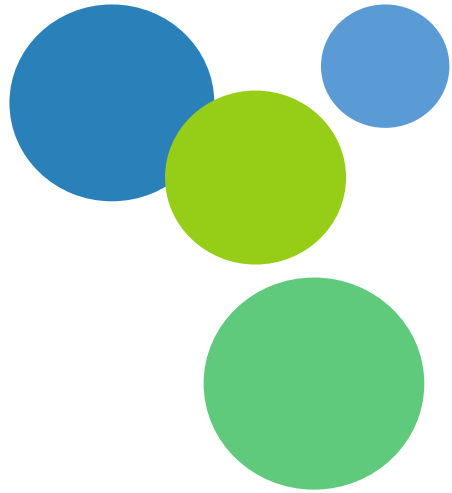
Healthy Life Trajectories Initiative



HeLTI Research Committee Meeting
February 18th, 2021

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Maelstrom Research
Research Institute of the McGill University Health Centre



What was achieved in 2020?

HeLTI harmonization documentation

HeLTI Prospective Harmonization Project



The objective of the Healthy Life Trajectories Initiative (HeLTI) prospective harmonization project is to identify a core set of common variables to be collected across the four participating countries (Canada, China, India and South Africa) to answer a wide range of research questions for the improvement of health, child development and the prevention of non-communicable diseases including obesity, diabetes, cardiovascular diseases and poor mental health.

Search Variables

Overview

Acronym	HeLTI-HP
Contacts	Julie Bergeron Research Institute of the McGill University Health Centre

Harmonization Study Design

The HeLTI project is composed of 4 randomized controlled trials: BUilding Knowledge and a foundation for HeALTHy Life trajectories (BUKHALI, South Africa), Early INterventions to Support Trajectories for healthy lifE in INdia (EINSTEIN, India), A Multifaceted Community-Family-Mother-Child Intervention Study for the Prevention of Childhood Obesity (SChELTI-LIFE TREE, China) and Trajectories of Healthy Life using Public Health and Primary Care Interventions in Canada (Canada).

The participants are followed-up at ten time points (one preconception, two during pregnancy, one at delivery and six from birth to five years of age).

1 Datasets

1 - 10 of 10

Search...

Name	Type	Variables
HeLTI Preconception Harmonized Dataset - Mothers	Harmonized Dataset	173
HeLTI Pregnancy visit 1 Harmonized Dataset - Mothers	Harmonized Dataset	165
HeLTI Pregnancy visit 1 Harmonized Dataset - Fathers	Harmonized Dataset	106
HeLTI Pregnancy visit 2 Harmonized Dataset - Mothers	Harmonized Dataset	202
HeLTI Delivery Harmonized Dataset - Mothers	Harmonized Dataset	11
HeLTI Delivery Harmonized Dataset - Children	Harmonized Dataset	53
HeLTI 3 months Harmonized Dataset - Mothers	Harmonized Dataset	71
HeLTI 3 months Harmonized Dataset - Children	Harmonized Dataset	109
HeLTI 6 months Harmonized Dataset - Mothers	Harmonized Dataset	46
HeLTI 6 months Harmonized Dataset - Children	Harmonized Dataset	109

Population

HeLTI Prospective Harmonization Project population

Women planning to become pregnant and aged over 18 years are recruited from Canada (Alberta, Ontario), China and South Africa. We recruit approximately 22,730 pregnant women (5,230 women in Canada, 4,700 in China, 6,800 in South Africa).

Information is collected about the mothers, their children and the fathers.

<https://www.maelstrom-research.org/mica/harmonization-study/helti-hp>

HeLTI harmonization documentation

Harmonization

Click on each status icon to get more details on the corresponding harmonization results :

- ✔ **Complete** - study-specific variable is the same as DataSchema variable (status = identical) or needs transformation to generate DataSchema variable (status = compatible)
- ✘ **Impossible** - study does not collect DataSchema variable (status = unavailable) or cannot be used to generate DataSchema variable (status = incompatible)
- ⚠ **Undetermined** - harmonization status not determined
- 🚫 **Not Applicable** - harmonization status is not relevant

Download

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Variable	BUKHALI	EINSTEIN	HeLTI Canada	SCHeLTI-LIFE TREE
LSB_SLE_PSQI_GLOBAL	✔	✔	✔	✔
LSB_SMK_CIG_PRESENT	✔	✔	✔	✔
SMK_CIG_PRES_QTY	✔	✔	✔	✔
LSB_ALC_PRESENT	✘	✔	✔	✔
LSB_ALC_BEER_QTY_PRESENT	✘	✔	✔	✔
LSB_ALC_BEER_UNITS	✘	✔	✔	✔
LSB_ALC_WINE_QTY_PRESENT	✘	✔	✔	✔
LSB_ALC_WINE_UNITS	✘	✔	✔	✔
LSB_ALC_LIQUOR_QTY_PRESENT	✘	✔	✔	✔
LSB_ALC_LIQUOR_UNITS	✘	✔	✔	✔
LSB_ALC_OTHER_QTY_PRESENT	✘	✔	✔	✔

Overview

Label	PSQI - Global score
Description	Global Score of the Pittsburgh Sleep Quality Index: Sum of seven components score
Harmonization Study	HeLTI-HP
Dataset	HeLTI Pregnancy visit 2 Harmonized Dataset - Mothers
Value Type	Integer
Variable Type	Harmonized

Classifications

Additional information	
Source	Questionnaire
Target	Participant
Areas of information	
Lifestyle and behaviours	Sleep
Constructs for life habits	
Constructs for sleep	Pittsburgh Sleep Quality Index

COVID-19 dataset

Variable name	Variable label	Variable description	Categories label/unit of the variable
SDC_WRK_ESS_SERV_CUR	Works in a essential service	Indicator of whether the participant is currently working in an essential service (i.e. healthcare, delivery worker, store worker, security, building maintenance).	0=No 1=Yes
DIS_COVID_SYMP	Has experienced any symptoms	Indicator of whether the participant has experienced any COVID-19 symptoms.	0=No 1=Yes
DIS_COVID_TESTED	Has been tested for COVID-19	Indicator of whether the participant has been tested for COVID-19.	0=No 1=Yes
DIS_COVID	Diagnosed with COVID-19	Indicator of whether the participant has been diagnosed with COVID-19.	0=No 1=Yes
DIS_COVID_DATE	Date of COVID-19 diagnosis	Date at which the participant has been diagnosed with COVID-19.	YYYY-MM-DD
EXP_COVID_SI	Currently or have been self-isolating	Indicator of whether the participant is currently or has been staying at home and restricting social interactions.	0=No 1=Yes
DIS_COV_HOSP	Hospitalized due to COVID-19	Indicator of whether the participant has been hospitalized due to COVID-19.	0=No 1=Yes
DIS_COV_HH	Anyone in the household diagnosed with COVID-19	Indicator of whether anyone living in the participant's household has been diagnosed with COVID-19.	0=No 1=Yes

Adverse events dataset

Excerpts from HeLTI DMC Charter

Table 1. Reportable Serious (Severe) Adverse Events

REPORTABLE SERIOUS (Severe) ADVERSE EVENTS	Definitions
Death	
Mother's death	
Child's death	
Stillbirth Neonatal Death	Stillbirth: Defined as birth of an infant that has died in the womb (strictly, after having survived through at least the first 28 weeks of pregnancy, earlier instances being regarded as abortion or miscarriage). Neonatal death: defined as death of a live born infant within the first 28 days after birth.
Persistent/significant disability/incapacity	
Is Life-threatening	
Maternal/Child ICU admission	Defined as admission in intensive care unit (adult or child) that was not transitory and lasted more than one hour.
Congenital anomaly/ birth defect	

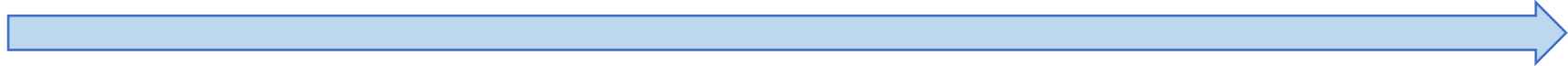
Table 2. Reportable Adverse Events

REPORTABLE ADVERSE EVENTS	Definitions
Child protective services involvement (voluntary or involuntary)	A set of government and private services designed to protect children and encourage family stability. The main aim of these services is to safeguard children from abuse and neglect.
Maternal/Child hospitalization	Defined as hospitalization >24 hours
Suicidal behaviour	Suicidal behaviours include any risk of attempt to inflict serious harm to self that may result in death.
Physical or sexual assault	A Physical Assault is the act of inflicting physical harm or unwanted physical contact upon a person or, in some specific legal definitions, a threat or attempt to commit such an action. Sexual Assault is defined as an assault of a sexual nature that violates the sexual integrity of the victim.
Homicidal behaviour	Any attempt to seriously injure or kill another person or ideations that represent a realistic threat to another person.

Overview of the harmonization work

25 meetings

November 2017



February 2021

To finalize

- Child's sleep 36-60 months
- Child's physical activity 12-60 months
- Development and behaviour assessments

1,824 core variables defined!

20 datasets

(1,214 core variables that will be collected across the 4 studies)

913 variables from standards

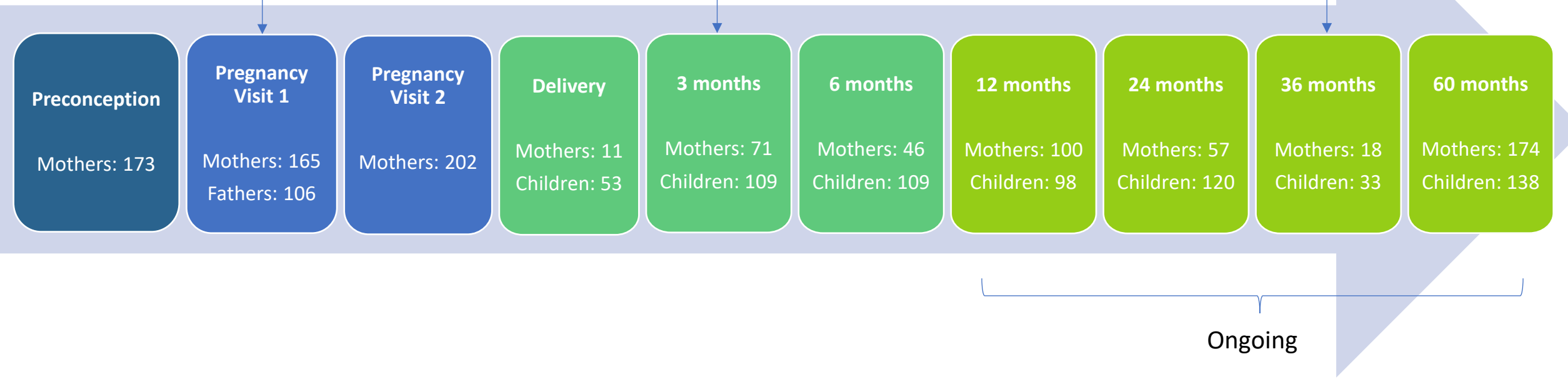
911 flexible variables

Overview of the harmonization work

Not in Canada

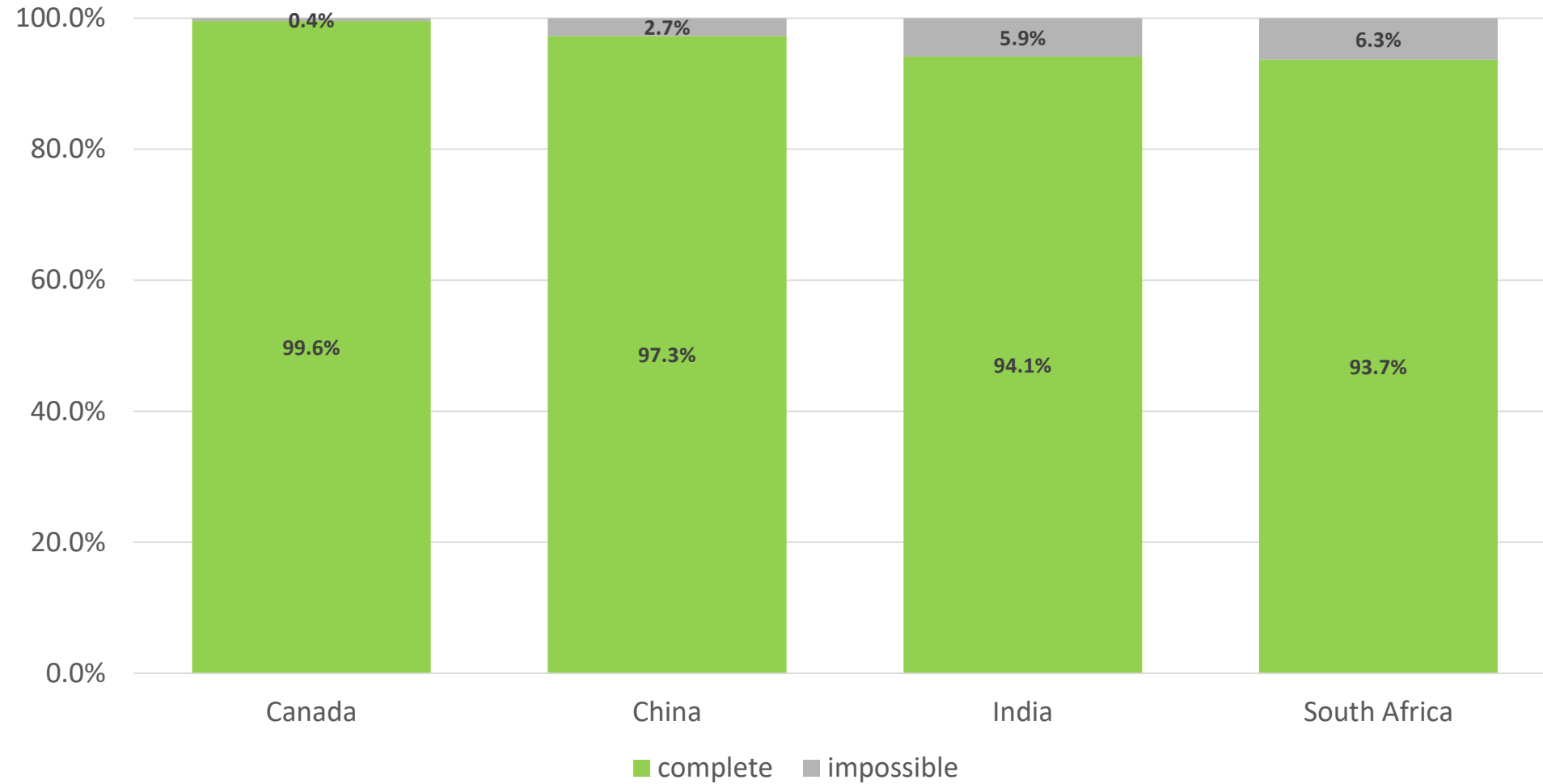
Not in South Africa

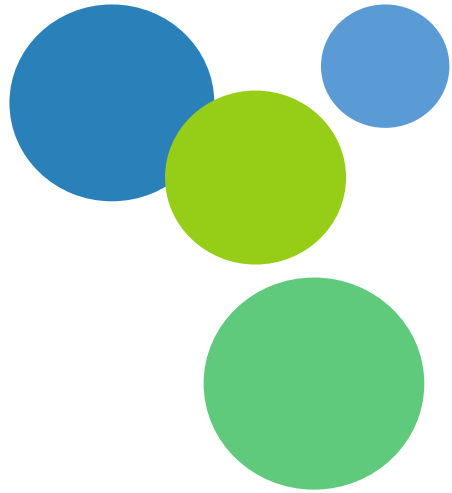
Not in South Africa



Ongoing

Harmonization overview by country across all time points



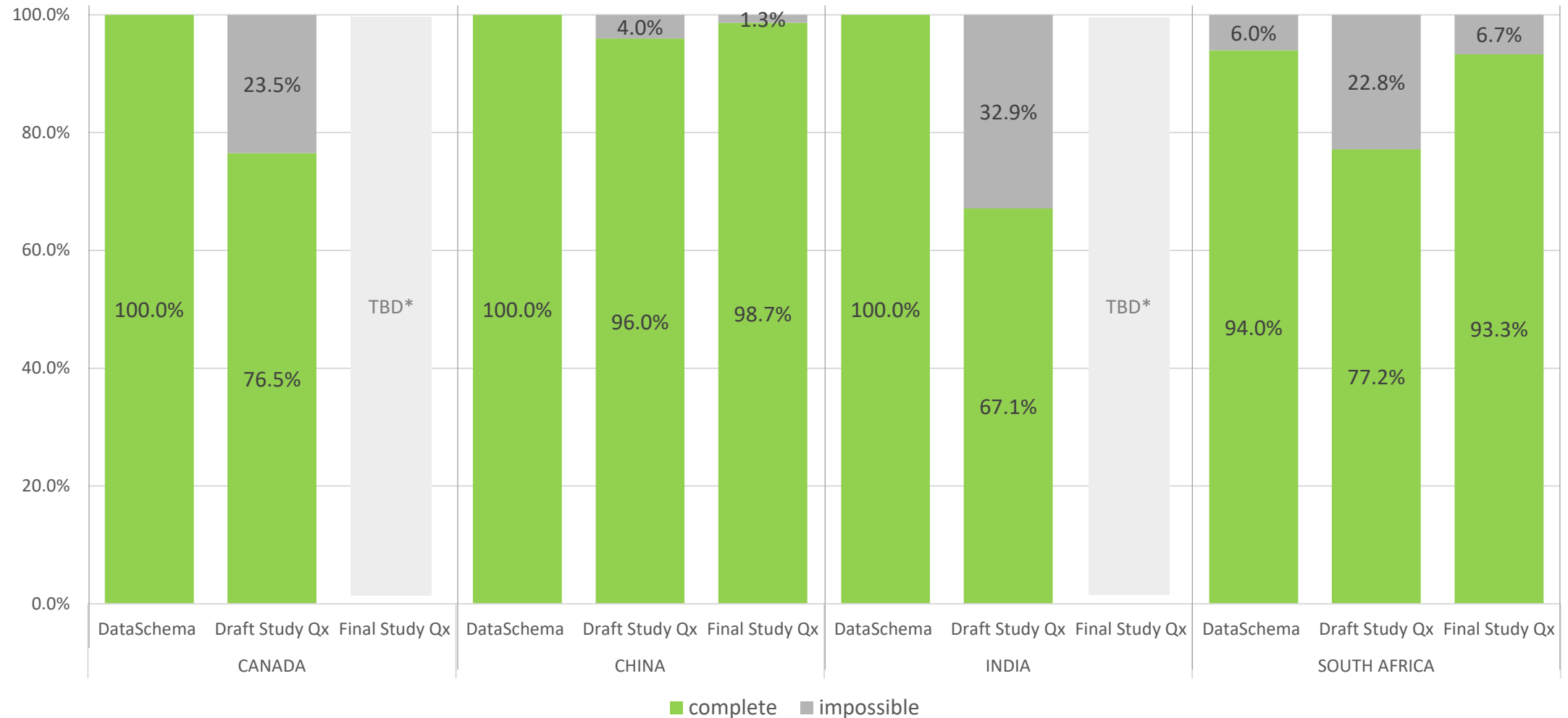


What's next?

Harmonization process

Steps	Objectives (harmonization)	Status
(1) Define the core variables	Help define the core variables and delineate if studies can collect the variables	Almost finalized
(2) Develop the questionnaires and operating procedures	Review the questions to identify if minor modifications could improve the harmonization potential	Partial (pre-conception)
(3) Collect data/samples	Studies	
(4) Prepare data processing	Generate the information required to process data under the core format (e.g., guidelines to treat outliers, processing algorithms)	To do
(5) Implement the data warehousing infrastructure	Studies (data could remain on local servers or pooled)	
(6) Process data under the core format	Support data processing to ensure optimal harmonization and generate the documentation required for users to properly understand harmonized data	To do
(7) Use the harmonized data	Studies	

(2) Harmonization potential for each country based on preconception questionnaires

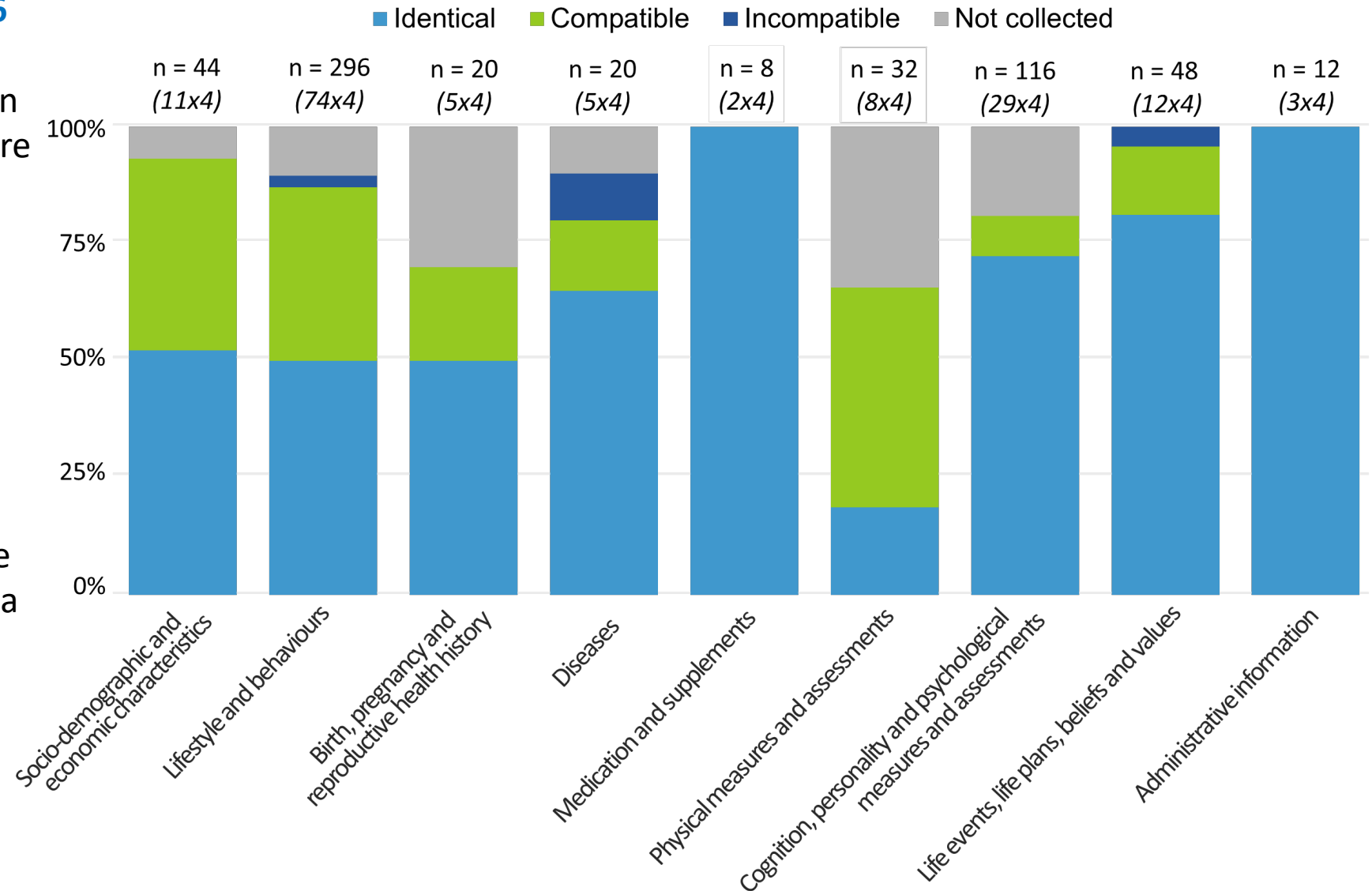


*To be determined

(2) Harmonization potential for different areas of information

Total number of variables : N=596

- **58 % (n=343)** of the variables in study-specific questionnaires are identical to the core variables.
- **28% (n=167)** of study-specific variables will require transformation under the common format.
- **65% (n=96)** of the core preconception variables will be available for the 4 countries in a compatible format.



(4) Prepare processing rules for compatible variables

CANADA

CHINA

INDIA

SOUTH AFRICA

Study-Specific information used to generate the core variable

Are you currently in paid employment?
 Yes, working full-time
 Yes, working part-time
 Yes, but currently on parental leave
 No, stay at home parent
 No, unemployed
 No, student

Are you currently in a paid employment?
 Yes
 No
If yes,
 Full time
 Part time

Information not collected by the study

Do you currently have a job?
 Yes
 No
(If yes) Was the job full time, or part time?
 Full-time
 Part-time

Proposed algorithm strategy

```
recode("Yes, working full-time"=="1",
      "Yes, work. part-time"=="1",
      "Yes, curr. on parental leave"=="1",
      "No, home parent"=="0",
      "No,unemployed"=="0", "No, student"=="0",
      "NA"==NA_character_)
```

```
case_when(
  $Currently in paid employment==Yes,
  ~ $Employment part-time or full time)
```

Information not collected by the study

```
case_when(
  $Currently in paid employment==Yes,
  ~ $Employment part-time or full time)
```

Core variable

Indicator of whether the participant is working part-time or full-time in a paid employment. (0=Part-time, 1=Full-time)

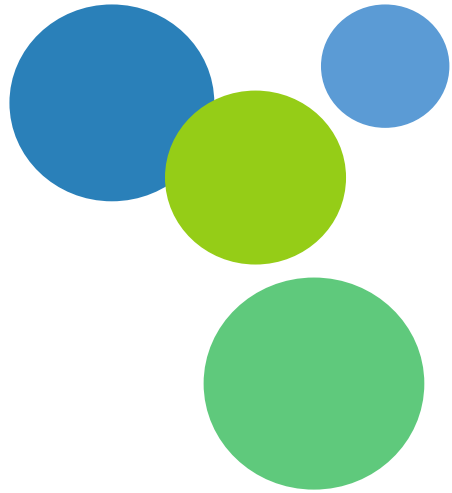
Summary of next steps

Maelstrom could provide support to:

- For each data collection events, review the *final* study-specific questionnaires and data dictionaries to evaluate the “definitive” harmonization potential
- Generate the information required to guide data processing under the core variables format (harmonization standard operating procedures and algorithms).
 - * *Data processing could be centralized or achieved by studies*

Also:

- Add study descriptions to the Maelstrom website to optimize the HeLTI catalogue
- Write paper about prospective harmonization process in HeLTI



Questions ?





Healthy Life Trajectories Initiative



THANK YOU!

On behalf of the harmonization
working group

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