



Release Notes

Core Information Standard

V2.01

Publication Date: April 2026

Previous Release: v2.0 August 2021

Safety relevant changes – data items relating to sex and gender

The following changes have been made to the clinical safety case report and hazard log:

- The Hazard Log has been updated to version 2.2.
- The Safety Case has been updated to version 1.8.
- New hazard created - Hazard 37 “Mis-interpretation of sex”.
- Replacement of hazard 16 “Sex data item may cause accidental disclosure of gender reassignment without consent” with new hazard “Recording an individual's 'Gender identity' alongside their 'Sex at birth (observed)' in their clinical record and displaying together along with 'Administrative gender' (derived from the Personal Demographics Service) may cause accidental disclosure of transgender, non-binary or gender diverse status causing psychological harm”.

Model and implementation guidance

The following changes have been made to the model and implementation guidance:

- Model uplifted from version 2.0 to 2.01 to align to minor release version including updated sex and gender data items.
- Section specific implementation guidance is now included in the model.
- Changes to the model as outlined below.

Summary - Information model changes in this release

Location	Data item	Update	Detail
Person demographics	<ul style="list-style-type: none"> Gender Sex 	Removal of data item(s)	<ul style="list-style-type: none"> Data items removed following consultation.
Person demographics	<ul style="list-style-type: none"> Sex at birth (observed) Administrative gender Gender identity Additional information about gender identity Pronouns 	Addition of data item(s)	<ul style="list-style-type: none"> Sex at birth (observed) is a mandatory data item. Administrative gender is a required read only legacy data item for England only to represent the data held on the Personal Demographics Service (PDS). All other new data items are required in the core information standard.

