

**Pregnancy Report and Outcome [PRN]**

01	Site awareness date: ⓘ Complete the Product Hold/Discontinuation CRF	___ / ___ / _____ (dd/mm/yyyy)
02	Is date of onset of last menstrual period known by the participant?	<input type="checkbox"/> Yes (answer 02a) <input type="checkbox"/> No, no menses <input type="checkbox"/> Unknown

ⓘ 02a. Complete if date of last menstrual period is known by the participant:

Date of onset of last menstrual period: ⓘ A complete date is required. Record best estimate if date not known.	___ / ___ / _____ (dd/mm/yyyy)
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03	Date of positive pregnancy test: ⓘ A complete date is required.	___ / ___ / _____ (dd/mm/yyyy)
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ⓘ **Questions 04 – 06a information can be gathered through self-reported medical history at the time the study staff became aware that the participant was/is pregnant.**

04	Estimated date of delivery:	___ / ___ / _____ (dd/mm/yyyy)
05	What information was used to estimate the date of delivery/gestational age?	<input type="checkbox"/> Last menstrual period <input type="checkbox"/> Initial ultrasound < 20 weeks <input type="checkbox"/> Initial ultrasound >= 20 weeks <input type="checkbox"/> Physical examination <input type="checkbox"/> Conception date by assisted reproduction <input type="checkbox"/> Other, specify (answer 05a)

ⓘ 05a. Complete if "other" information was used to estimate the date of delivery/gestational age:

Other, specify: _____
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06	Has the participant ever been pregnant before?	<input type="checkbox"/> Yes (answer 06a) <input type="checkbox"/> No
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ⓘ 06a. Complete if the participant has ever been pregnant before:

Number of full-term live births (>= 37 weeks):	_____
Number of premature live births (< 37 weeks):	_____
Number of living children:	_____
Number of spontaneous abortions (< 20 weeks), ectopic pregnancies and/or elective abortions:	_____
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment?	<input type="checkbox"/> Yes <input type="checkbox"/> No

07	Has the participant been referred or received antenatal care?	<input type="checkbox"/> Yes (answer 07a) <input type="checkbox"/> No
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ⓘ 07a. Complete if the participant has been referred for or received antenatal care:

If yes, list clinic (also indicate if private or public): _____
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**Pregnancy Report and Outcome (continued)**

08	Is the outcome of this pregnancy obtainable? ⓘ If it is determined that an outcome is not obtainable (e.g., the participant refuses further contact), mark "No". Note rationale in Comments, Q19.	<input type="checkbox"/> Yes <input type="checkbox"/> No (skip to end of form comments)
09	How many pregnancy outcomes resulted from this reported pregnancy?	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 or more
10	Place of delivery:	<input type="checkbox"/> Home <input type="checkbox"/> Hospital <input type="checkbox"/> Clinic <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify (answer 10a)

ⓘ 10a. Complete if place of delivery was marked "Other, specify":  
 Other, specify: \_\_\_\_\_

**ⓘ Outcome #1:**

11	Outcome #1 date:	__ / __ / ____ (dd/mm/yyyy)
12	Specify outcome #1: ⓘ Mark only one.	<input type="checkbox"/> Full term live birth (>= 37 weeks) (answer 12a) <input type="checkbox"/> Premature live birth (< 37 weeks) (answer 12a) <input type="checkbox"/> Spontaneous fetal death and/or still birth (>=20 weeks) <input type="checkbox"/> Spontaneous abortion (< 20 weeks) <input type="checkbox"/> Ectopic pregnancy

ⓘ 12a. Complete if outcome #1 was "Full term live birth (>= 37 weeks)" or "Premature live birth (< 37 weeks)":

Method of outcome #1:	<input type="checkbox"/> Vaginal <input type="checkbox"/> C-section <input type="checkbox"/> Operative (forceps, vacuum)
Birth weight (kg):	_____
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female

13	Were there any complications related to pregnancy outcome #1? ⓘ if applicable and if "Yes", complete AE Log.	<input type="checkbox"/> Yes <input type="checkbox"/> No
14	Were any fetal/infant congenital abnormalities identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not assessed

**Pregnancy Report and Outcome (continued)**

**! Outcome #2. If only one outcome, skip to comments, Q19.**

<b>15</b>	Outcome #2 date:	____ / ____ / _____ (dd/mm/yyyy)
<b>16</b>	Specify outcome #2:  <i>! Mark only one.</i>	<input type="checkbox"/> Full term live birth (>= 37 weeks) (answer 16a) <input type="checkbox"/> Premature live birth (< 37 weeks) (answer 16a) <input type="checkbox"/> Spontaneous fetal death and/or still birth (>=20 weeks) <input type="checkbox"/> Spontaneous abortion (< 20 weeks) <input type="checkbox"/> Ectopic pregnancy

**! 16a. Complete if outcome #2 was "Full term live birth (>= 37 weeks) or "Premature live birth (< 37 weeks)":**

Method of outcome #2:	<input type="checkbox"/> Vaginal <input type="checkbox"/> C-section <input type="checkbox"/> Operative (forceps, vacuum)
Birth weight (kg):	_____
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female

<b>17</b>	Were there any complications related to pregnancy outcome #2?  <i>! if applicable and if "Yes", complete AE Log.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>18</b>	Were any fetal/infant congenital abnormalities identified?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not assessed

<b>19</b>	Comments:  <div style="border: 1px solid black; border-radius: 20px; height: 200px; margin-top: 10px;"></div>
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CRF Completed By: \_\_\_\_\_ (initials)

CRF Completion Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_\_ (dd/mm/yyyy)