INSTRUCTIONS:

At study entry: Record any pregnancy complications during the index pregnancy up to the time of enrollment.

At delivery: Record any new pregnancy complications that occur during the index pregnancy from the time of enrollment up to 14 days postpartum that have not been previously reported.

For subsequent pregnancies: Record any pregnancy complications identified during the subsequent pregnancy or up to 14 days postpartum.

Any pregnancy complications reported on this form that meet protocol-defined AE criteria per Protocol Section 7.2 must also be

reported on the ADE10002: Adverse Event Log (Multi). **INSTRUSTIONS04** Are there any new targeted pregnancy diagnoses that are required to be reported? **PREGDIAGYN** Indicate what type of pregnancy the diagnoses are being reported for: Index **PREINDSUB** Subsequent Indicate if any of the following have been diagnosed: **HEADER** Was maternal Zika virus infection suspected or confirmed during the current ZIKAYN pregnancy? Provide a narrative surrounding the condition [400]: COVAL ZIKA Diagnosis: Abortion, spontaneous/miscarriage CETERM DIAG Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. 1 FAORRES GESTWKS Diagnosis: CETERM_DIAG Abortion, therapeutic Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. FAORRES GESTWKS Diagnosis: Bleeding, vagina CETERM_DIAG Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. 1 FAORRES GESTWKS Diagnosis: Cord prolapse **CETERM DIAG** Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. 1 FAORRES GESTWKS Diagnosis: Febrile morbidity **CETERM DIAG** Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. 1 FAORRES GESTWKS Diagnosis: **Eclampsia** CETERM_DIAG Diagnosed? **CETERMYN** Number of completed gestational weeks at time of onset [nn]. ¹ FAORRES GESTWKS Diagnosis: Pre-eclampsia **CETERM DIAG** Diagnosed? **CETERMYN**

Number of completed gestational weeks at time of onset [nn].1	FAC	ORRES_GESTV	VKS
Diagnosis:	CE	TERM_DIAG	HELLP syndrome
Diagnosed?	CETERMYN		
Number of completed gestational weeks at time of onset [nn].1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Hypertens	sion, chronic, in pregnancy
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Hyperto	ension, pregnancy-induced
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Не	matoma, vaginal or vulvar
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FAC	ORRES_GESTV	VKS
Diagnosis:	CETERM_DIAG	Hemo	orrhage with hemodynamic instability, intrapartum
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	VKS
Diagnosis:	CETERM_DIAG	Hemorrhage rec	quiring surgical procedure, intrapartum
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Hemorr	hage requiring transfusion, intrapartum
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	VKS
Diagnosis:	CETERM_DIAG	Hemo	orrhage with hemodynamic instability, postpartum
Diagnosed?	C	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	VKS
Diagnosis:	CETERM_DIAG	Hemorrhage rec	quiring surgical procedure, postpartum
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Hemorr	hage requiring transfusion, postpartum
Diagnosed?	C	ETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAC	ORRES_GESTV	/KS
Diagnosis:	CETERM_DIAG	Incompetent ce	rvix, prophylactic cerclage
Diagnosed?	C	ETERMYN	

Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG Incompetent	cervix, emergent cerclage
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG Incom	petent cervix, no cerclage
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Intrauterine fetal demise
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG Intrauterine	growth restriction (IUGR)
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Significant growth lag
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Oligohydramnios
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Polyhydramnios
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Placenta, abruptio
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn].	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Placenta accreta
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Placenta increta
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Placenta percreta
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTW	KS
Diagnosis:	CETERM_DIAG	Placenta previa

Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Placenta, unspecified
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Pregnancy, ectopic
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FA	ORRES_GEST\	NKS
Diagnosis:	CE	ETERM_DIAG	Pregnancy, post-term
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Preterm labor
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FA	ORRES_GEST\	WKS
Diagnosis:	CETERM_DIAG	Premature rup	ture of membranes, preterm
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FA	ORRES_GEST\	WKS
Diagnosis:	CETERM_DIAG	Premature 1	rupture of membranes, term
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Preterm delivery
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn].1	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Uterine atony
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FA	ORRES_GEST\	NKS
Diagnosis:	CE	ETERM_DIAG	Uterine inversion
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FA	ORRES_GEST\	NKS
Diagnosis:	CE	ETERM_DIAG	Uterine rupture
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FA	ORRES_GEST\	NKS
Diagnosis:	CE	TERM_DIAG	Uterine scar dehiscence
Diagnosed?	(CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FA	ORRES_GEST\	NKS

Diagnosis:	CETERM_DIAG Group B st		B streptococcal infection
Diagnosed?	CETERMYN		
Number of completed gestational weeks at time of onset [nn]. ¹	FAORRES_GESTWKS		(S
Diagnosis:	CETERM_DIAG	(Cholestasis of pregnancy
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTW	(S
Diagnosis:	CETERM_DIAG	Pruritic urticaria	al papules and plaques of pregnancy (PUPPS)
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTW	(S
Diagnosis:	CET	ERM_DIAG	Uterine leiomyoma
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTWK	(S
Diagnosis:	CET	ERM_DIAG	Pyelonephritis
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTWK	(S
Diagnosis:	CETERM_DIAG	Urinary tra	act infection (lower tract)
Diagnosed?	CETERMYN		
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTWKS		(S
Diagnosis:	CETERM_DIAG	Any sexually tra	nsmitted infection (other than HIV)
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAO	RRES_GESTW	(S
Diagnosis:	CET	ERM_DIAG	Bacterial vaginosis
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTWK	(S
Diagnosis:	CET	ERM_DIAG	Significant trauma
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAO	RRES_GESTWK	(S
Diagnosis:	CET	ERM_DIAG	Gestational diabetes
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAO	RRES_GESTWK	(S
Diagnosis:	CET	ERM_DIAG	Chorioamnionitis
Diagnosed?	CE	TERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAO	RRES_GESTWK	(S
Diagnosis:	CET	ERM_DIAG	Cervicitis

Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. ¹	FAORRES_GESTWK	S
Diagnosis:	CETERM_DIAG	Fatty liver
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTWK	S
Diagnosis:	CETERM_DIAG C	esarean wound infection
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTWK	S
Diagnosis:	CETERM_DIAG	Endometritis
Diagnosed?	CETERMYN	
Number of completed gestational weeks at time of onset [nn]. 1	FAORRES_GESTWK	S

For example, if time of onset was at 23 weeks and 4 days, report 23 weeks. If diagnosed postpartum, leave this field blank.

Form: EVW10003: Pregnancy Record

1 What is the estimated date of conception?		CESTDTC	
2 How was the estimated date of conception determined?		ORRES_DETR	Last menstrual period
			Initial ultrasound
			Physical examination
			Assisted reproduction
			Other
a If Other, specify [100]:	FA	ORRES_DETROTH	

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Form: EVW10012: IMPAACT 2010 Last Menstrual Period and Ultrasound Information

Last Menstrual Period Information:	HEADER06	
Does the mother know the date of the first day of her last menstrual period?	LAMPOTPATYAL	Yes
	LMPSTDATYN	No
What is the date of the first day of the mother's last menstrual period? Date		
abbreviation for the month. For example, 15/JAN/2015. A complete date is p event is unknown, report the month and year: un/MMM/yyyy.	oreferred for the last menstrual period di RPORRES_LMPSTDTC	ate. If the day of the
Is the mother certain about this date?	LMPSTDAT_CERTAIN	Yes
		No
Ultrasound Information: Complete this section using information from the	earliest ultrasound available.	DER02
Date of scan:	PRDAT_ULTRA	
Number of fetuses [n]:	FAORRES_FETUSNO	
Gestational age on date of this scan (completed weeks) [nn]:	FAORRES_GESTAGEWK	
Gestational age on date of this scan (completed days) [n]:	FAORRES_GESTAGEDY	
Estimated date of delivery based on this scan:	FAORRES_ESTDELIVDAT	
Fetus	FETUSABC	A
		В
		$_{\rm c} \simeq$
Was fetal heart beat present?	FAORRES HEARTTONES01	Present
······ ·······························	171011120_112711111111111111111111111111	Absent
		Not evaluated
Fetal weight (g) [nnnn]	FAORRES_FETALWEIGHT	Fixed Unit: g
Crown-rump length (cm) [nnn.nn]	FAORRES_CROWNRUMP01	Fixed Unit: cm
This field is only required when gestational age is between 6-13 weeks.		
Femur length (mm) [nnn.n]	FAORRES FEMURLTH01	Fixed Unit: mm
This field is only required when gestational age is 14 or more weeks.		
Abdominal circumference (cm) [nnn.nn]	FAORRES ABCIRC01	Fixed Unit: cm
This field is only required when gestational age is 14 or more weeks.	TAGRICEO_ABOILOGT	1 1110 0 11111 0111
Biparietal diameter (mm) [nnn.n]	FAORRES_BIPARDIA01	Fixed Unit: mm
This field is only required when gestational age is 14 or more weeks.	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Head circumference (cm) [nnn.nn]	FAORRES HEADCIRC01	Fixed Unit: cm
This field is only required when gestational age is 14 or more weeks.	TACKKES_HEADCINCOT	Tixed Cilit. Cili
Were any fetal anomalies identified?	FETALANOMYN01	Yes
were any retair anomaines identified.	FE IALANOWITHOT	\cup
		No
If Yes, specify [200]:	FAORRES_FETALANOM01	
Are there any comments regarding this obstetrical ultrasound?	ULTRACOMYN01	Yes
		No
If Yes, specify [200]:	COVAL ULTRA01	

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Form: EVW10013: IMPAACT 2010 Pregnancy Outcome Log

INSTRUCTIONS:

· When reporting a subsequent pregnancy, leave the Infant PID number field blank and indicate which fetus/infant this is being completed for. **HEADER1** • In the case of multiple births, add a new log line for each fetus/infant. Number of fetuses/infants: PREGOUT MULTI **NOTE:** If molar pregnancy or false positive, select '0'. Infant PID Number: If completing this log line for a subsequent pregnancy, leave "Infant PID" field blank **INFUSUBJID** Indicate which fetus/infant this is being completed for: APDM APID NA NOTE: If molar pregnancy or false positive, select 'Not Applicable'. Not applicable Indicate outcome: Live birth Stillbirth/Intrauterine fetal demise (IUFD \geq 20 weeks) Spontaneous abortion (< 20 weeks) Induced abortion (therapeutic or elective) Ectopic pregnancy **FAORRES PREGOUT** Molar pregnancy False positive/No pregnancy **CEENDAT** Provide date of delivery/outcome: Provide a brief narrative of circumstances [200]: COVAL PREGOUT FAORRES SUBGESTWK Estimated gestational age at time of pregnancy outcome (completed weeks) [nn]: Estimated gestational age at time of pregnancy outcome (completed days) [n]: FAORRES_SUBGESTDY When was stillbirth diagnosed? Prior to labor FASTRTPT STILLBORN During labor At delivery Unknown If stillborn, were macerated skin changes noted? FAORRES MACERATED Unknown

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Form: EVW10015: IMPAACT 2010 Labor Record

1 Number of fetuses:	EAODDEC MULTI	10
	FAORRES_MULTI	$\stackrel{2}{\longrightarrow}$
2 Was the mother in labor prior to delivery?		Yes
•	FAORRES INLABOR	No
	TAORITEO_INEADOR	Unknown
a Enter the date labor began:	FAORRES_LABORSTDAT	
b Enter the time labor began: Record times using the 24-hour clock	FAORRES_LABORSTTIM	
3 How long prior to delivery did labor begin?		0-<4 hours
		4-<6 hours
	FAORRES_LABORPRIOR	6-<12 hours
		12-24 hours
		>24 hours
		Unknown
4 Did the membranes rupture prior to active labor?	FAORRES RUPTURE	Yes
	TAORRES_ROTTORE	N_0
5 Was labor spontaneous or induced?	EAGEDES LABORTYD	Spontaneous
•	FAORRES_LABORTYP	Induced
a If Induced, what is the primary indication for induction?	Gestational l	nypertension (e.g.,
	pre-eclampsia, ec	lampsia, HELLP)
	Worsening maternal chr	
		Chorioamnionitis
		st-term pregnancy
	Fetal	growth restriction
	FAORRES_INDIND	Oligohydramnios
	41	Isoimmunization
		ormal fetal testing
		Multiple gestation
		tasis of pregnancy
	Choics	Fetal death
	Prolonged rupture of me	
	Other maternal ch	
	diabetes mellitus, rena	al disease, chronic
		almonary disease) naternal indication
		er fetal indication
h If Other creeds, [70]	FAORRES_INDINDOTHSP	
b If Other, specify [70]: 6 Did the mother experience any adverse events during labor and delivery		Yes
Refer to Protocol Section 7.2 and enter adverse events that meet protocol-s		No
into the ADE10002: Adverse Events Log.	AEYN MOTHERLABOR	Unknown
	_	

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Form: EVW10015: IMPAACT 2010 Labor Record

7 Were any concomitant medications taken during labor and delivery?		Yes
Refer to protocol Section 6.11 and enter concomitant medications that meet protocol-specified reporting		
requirements into the CMW10001: IMPAACT 2010 Concomitant Medications Log.	FAORRES_LABORDRUG	Unknown
8 Were any corticosteroids given for preterm labor at any point during this pregnancy?	CORTICOSTEROIDSYN	Yes No
If Yes, go to the CMW10001: Concomitant Medications Log and enter any corticos preterm labor.	teroids given for	Unknown

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Form: EVW10018: IMPAACT 2010 Delivery Record (Infant Enrolled)

1 Is information available about the delivery?		DELI	/INFOYN	Yes
				No
2 Infant PID Number:		INFU	ISUBJID	
3 What is the infant's date of birth?		BR [*]	THDAT	
4 What is the infant's time of birth? Record times using the 24-	hour clock	BR	THTIM	
5 What is the sex of the infant?			SEX	Male
				Female
			Ambiguous	genitalia/Intersex
				Unknown
6 Type of delivery:		FAORRES	_DELIVTYP p	ontaneous vaginal
				Assisted vaginal
				Elective cesarean
			En	nergency cesarean
a What was the primary indication for the cesarean section?	FAORRES	CESINDC	Protraction and	l/or arrest of labor
1 ,	TAGRICLO	_02011100		Fetal distress
				Malpresentation
				Previous cesarean
		Placenta previa		
				Placenta abruptio
		Redu	action of MTCT ri	sk (e.g. detectable
				iternal HIV RNA)
			Genital herpes sin	· ` `
		D 1	1	Failed induction
		Prolor	nged rupture of me	
			Pre-eci	ampsia/Eclampsia
			,	Cord prolapse
			Ţ	Multiple gestation
				Fetal anomaly
			C-1	Macrosomia
			•	ject request/desire
Other maternal indic		er fetal indication		
				- Tetal indication
b If Other, specify [70]:			OTHSPECIFY	
7 Presentation:		FAORRE	S_PRESENT	Vertex
				Breech
				Transverse

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Form: LBW10005: Pregnancy Test

1 Was a pregnancy test performed?	LBPERF	Yes
a If No, specify reason not done [70]:	LBREASND_ALL	
2 Specimen Type:	LBSPECPREG	Serum Urine
3 Test Result:	LBORRESPREG	Negative Positive
4 Specimen Date:	LBDAT	

[LBW10005] IMPAACT 2010 Pg. 51

Form: LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log

INSTRUCTIONS: Complete a log line for each prior pregnancy.		
Is the outcome date known?	OUTCOMEDATKNO	Yes
If Yes, complete "Outcome date of prior pregnancy." If No, provide the best estimate of the outcome date of the prior pregnancy.		No
Outcome date of prior pregnancy	CEENDAT_PRIOR	
Estimate of when prior pregnancy outcome occurred	CESTRTPT_OUTCOME	Before
		During
		After
		Unknown
Estimate year when prior pregnancy outcome occurred	CESTTPT_OUTCOMEY	R
Indicate outcome of prior pregnancy	FAORRES_PRIOROUT	Live birth
	Stillbirth/Intrauterin	e fetal demise (IUFD ≥ 20 weeks)
	Spontaneous a	abortion (< 20 weeks)
	Induced abortion (th	erapeutic or elective)
		Ectopic pregnancy
		Molar pregnancy
	False p	ositive/No pregnancy
Did neonatal death occur before 28 days of age?	FAORRES_NEONAT	Yes
This question is only required when prior pregnancy outcome is "Live birth".		No

Form: OBW10000: IMPAACT 2010 Obstetrical History

Is the participant's pre-pregnancy weight available?		Yes
	PWEIGHTYN	No
If Yes, enter the participant's pre-pregnancy weight [nnn.nn]	VSORRES_PWEIGHT	
Weight unit:		Grams (g)
	VSORRESU_PWEIGHT	Kilograms (kg)
		Pounds (lb)
Date of pre-pregnancy weight: Dates are reported in the format dd/MMM/yyyy with a three-letter abbreviation for the month. For		
example, 15/JAN/2015. A complete date is preferred for the pre-pregnancy weight	ght. VSDAT_PWEIGHT	
How many pregnancies, including the current pregnancy, has this participant has complete form LGW10001: IMPAACT 2010 Prior Pregnancy Outcome Log for each		cies is greater than 1, RRES_PREGNN

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Form: OBW10001: IMPAACT 2010 Obstetrical Exam

Obstetrical Exam:	
Date of exam:	FADAT_OBS
Fundal height (cm) [nnn.n]:	FAORRES_FUNHEIGHT