Table 1. Descriptive Summary of Inclusion Criteria for Study Participation for Both Study Sites

Inclusion Criteria
For pregnant and nonpregnant women
Pregnant and non-pregnant women, as determined by medical history, 18 - 45 years of age inclusive
Intention of receiving Tdap vaccine
Willing to provide written informed consent prior to initiation of any study procedures
English or Spanish literate
Intention of being available for entire study period and complete all relevant study procedures
For pregnant women only
Singleton gestation ≥ 20 weeks 0 days gestation - ≤34 weeks 0 days gestation based on reconciliation of last menstrual period and ultrasound dating*

*Estimated due date (EDD) and Gestational Age (GA) - EDD will be based on reconciliation of a "sure" first day of the last menstrual period (LMP) and earliest dating ultrasound. If the LMP is uncertain, then the earliest dating ultrasound will be used to determine EDD and GA. If the ultrasound derived-EDD is in agreement with sure-LMP derived EDD, then the LMP-derived EDD is used to determine GA. If the ultrasound derived EDD is not in agreement with the LMP-derived EDD, the ultrasound-derived EDD is used to determine GA.

Table 2. Descriptive Summary of Exclusion Criteria for Study Participation for Both Study Sites

Exclusion Criteria
For pregnant and nonpregnant women
Febrile illness within the last 24 hours or an oral temperature (≥ 100.4^{o}F (≥ 38^{o}C) prior to Tdap administration
Severe allergic reaction (e.g., anaphylaxis) to any component of Tdap or any other diphtheria toxoid, tetanus toxoid and pertussis antigen containing vaccine
Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous pertussis antigen-containing vaccine
Known or suspected impairment of immunologic function including active infection with HIV, hepatitis B or C, current use of glucocorticoids[3], i.e., oral, parenteral, and high-dose inhaled steroids, and immunosuppressive or cytotoxic drugs
Receipt of any licensed vaccine OR investigational product within 1 week prior to Tdap vaccination in this study or planning receipt of any vaccines during 8-day post-vaccination period[1]
Any woman receiving an investigational vaccine or live vaccine inadvertently at any time during pregnancy will be excluded from analysis[2]

	Any condition which, in the opinion of the investigators, may pose a health risk to the subject or interfere with the evaluation of the study objectives
	Anyone who is a relative of any research study personnel
	Anyone who is an employee of any research study personnel
	Anyone who is already enrolled or plans to enroll in another clinical trial with an investigational product within 30 days of Tdap receipt. Co-enrollment in observational or behavioral intervention studies are allowed at any time while enrollment in a clinical trial involving an investigational product (other than vaccine) may occur after 30 days following Tdap receipt.
For pregnant women only	
	Tdap/Td/TT receipt during current pregnancy prior to study enrollment
	Any woman receiving an investigational vaccine or live vaccine inadvertently at any time during pregnancy will be excluded from analysis[2]
	Signs or symptoms of active preterm labor, defined as regular uterine contractions with cervical change[3]
For non-pregnant women only	
	Intention of becoming pregnant during study participation

[1]Receipt of inactivated vaccines during pregnancy, including routinely recommended inactivated influenza vaccine, given as part of usual care, is not an exclusion for this study, except during the 1 week prior to and 8 days after Tdap vaccination

[2]Note, inadvertent receipt of licensed HPV vaccine or any other inactivated licensed vaccine outside of the parameters specified above is not a reason for exclusion.

[3]Note, if a woman were to require antenatal corticosteroids for benefit of fetal lung maturity within 8 days post enrollment, she would not be excluded from the study for reactogenicity analysis. However, if antenatal corticosteroids were received anytime between vaccination and 28-day sample collection for serologic studies, she would be excluded from serologic studies as they could be altered by steroid receipt.

Table 3: Local Injection-site Reactogenicity

Symptom	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Pain	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism
Tenderness	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism
Induration/ Swelling	<10 mm	10-34 mm	>=35 mm
Erythema	<10 mm	10-34 mm	>=35 mm

Table 4: Systemic Reactogenicity ** Oral temperature, no recent hot/cold beverages or smoking.*

Systemic	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)
Fever (°C)*	≥ 37.8 - < 38° C ≥ 100 - < 100.4° F	≥ 38 - < 39° C ≥ 100.4 - < 102.2° F	≥ 39° C ≥ 102.2° F
Malaise	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism
Body aches (myalgias)	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism
Headache	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism
Feverishness	Noticeable but does not interfere with activity	Interferes with activity but did not necessitate medical visit or absenteeism	Prevents daily activity and resulted in medical visit or absenteeism

Table 5. Geometric Mean Titers among Pregnant Women with and without Prior Tdap Receipt

	Tdap Before			No Tdap Before			No Tdap before/ Tdap before		P Value
	N	GMT	95%CI (lower, upper)	N	GMT	95%CI (lower, upper)	GMT Ratio	95%CI (lower, upper)	T test
PT at Day 0	194	9.9	8.8, 11.2	100	7.4	6.4, 8.4	0.7	0.6, 0.9	<0.01*
PT at Day 28	194	46.2	39.9, 53.4	100	38.4	31.6, 46.7	0.8	0.7, 1.1	0.14
FHA at Day 0	194	30.8	26.3, 36.0	100	20.1	16.1, 25.1	0.76	0.5, 0.9	<0.01*
FHA at Day 28	194	103.7	91.6, 117.3	100	119.9	102.5, 140.3	1.2	0.9, 1.4	0.15
FIM at Day 0^	190	99.8	79.5, 125.2	99	42.8	30.0, 60.9	0.4	0.3, 0.6	<0.01*
FIM at Day 28^	190	693.9	601.7, 800.2	99	949.8	739.4, 1220.0	1.4	1.1, 1.8	0.03*
PRN at Day 0	194	40.5	33.8, 48.6	100	21.7	16.5, 28.5	0.5	0.4, 0.7	<0.01*
PRN at Day 28	194	228.1	199.4, 260.9	100	306.1	239.7, 390.8	1.3	1.0, 1.7	0.04*
Tetanus at Day 0	194	1.6	1.4, 1.8	100	0.9	0.8, 1.3	0.6	0.5, 0.8	<0.01*
Tetanus at Day 28	194	8.2	7.4, 9.2	100	10.7	9.0, 12.7	1.3	1.1, 1.6	0.01*
Diphtheria at Day 0	194	0.3	0.3, 0.4	100	0.2	0.1, 0.2	0.5	0.4, 0.7	<0.01*
Diphtheria at Day 28	194	1.7	1.5, 1.9	100	1.7	1.4, 2.2	1.0	0.8, 1.3	0.9

PT: pertussis toxin; **FHA**: filamentous hemagglutinin; **FIM**: fimbriae types 2 and 3; **PRN**: pertactin

GMT refers to geometric mean titer of antibody to respective antigens

Day 0 represents serology drawn before vaccination. Day 28 is 28 days after vaccination.

^Analyzed subjects receiving Adacel® only

*Statistically significant (p <0.05)