Reading Hospital
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Short Title	A Phase 3 Trial to Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy
Principal Investigator	Mark Martens, MD
Sub-Investigators	Xuezhi Jiang, MD Michelle Williams-Robinson, MD
Study Objective	To assess the safety and efficacy of respiratory syncytial virus (RSV) stabilized prefusion F subunit vaccine (RSVpreF) in pregnant women and infants.
Inclusion Criteria	• Healthy women ≥18 and ≤49 years of age who are between 24 and 36 weeks of gestation on the day of planned vaccination, with an uncomplicated, singleton pregnancy • Had an ultrasound examination performed at ≥18 weeks of pregnancy with no significant fetal abnormalities observed • Documented negative HIV antibody test, syphilis test, and hepatitis B virus (HBV) surface antigen test during this pregnancy
Exclusion Criteria	• Pre-pregnancy body mass index (BMI) of >40 kg/m^2 • Current pregnancy resulting from in vitro fertilization • Current pregnancy complications or abnormalities at the time of consent such as: pre-eclampsia, eclampsia, uncontrolled gestational hypertension, placental abnormality, significant bleeding or blood clotting disorder, endocrine disorders • Prior pregnancy complications or abnormalities at the time of consent such as prior pre-term delivery ≤34 weeks' gestation, prior stillbirth or neonatal death, previous infant with a known genetic disorder or significant congenital anomaly • Current alcohol abuse or illicit drug use

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Affiliations & Sponsors	Pfizer
Status	Open to Enrollment
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