

## The AZALEA Clinical Trial in Pregnancies at Risk for Severe Hemolytic Disease of the Fetus and Newborn (HDFN)

The AZALEA clinical trial is being conducted to assess the effectiveness and safety of an investigational medication when compared to placebo in decreasing the risk of fetal anemia with live neonates in pregnant participants at risk for severe hemolytic disease of the fetus and newborn.

### You may want to explore the AZALEA study if you are:

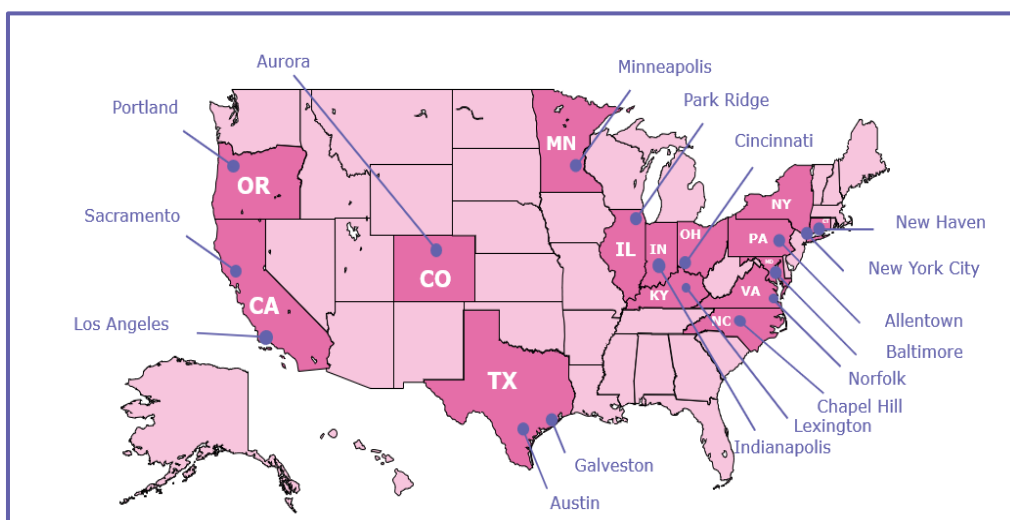
- 18-45 years of age
  - Currently pregnant \* with an estimated gestational age (GA) from Week 13<sup>0/7</sup> to Week 18<sup>6/7</sup> at enrollment
- \*Those who are currently planning a pregnancy are encouraged to contact a study site. Early screening is critical to enrollment.
- History of severe HDFN in a prior pregnancy, defined as:
    - Documented fetal anemia or fetal hydrops or received  $\geq 1$  IUT, as a result of HDFN (OR)
    - Fetal loss or neonatal death as a result of HDFN, with maternal alloantibody titers for RhD, Kell, Rhc, RhE, or RhC antigen above the critical levels (anti-Kell  $\geq 4$ ; other  $\geq 16$ ) and evidence of an antigen-positive fetus.

If you are interested in participating, the trial physician or staff will review additional information with you to assess your suitability. AZALEA may not be a suitable option if you have received or are planning to receive plasmapheresis, immunoadsorption therapy, intravenous immunoglobulin (IV Ig), or any immunoglobulin (Ig)G fragment crystallizable (Fc)-related protein therapeutics during the current pregnancy.

**What does trial participation involve?** All participants receive weekly intravenous infusions (of the active investigational medication or the placebo) for up to 23 weeks during pregnancy. Participants have a 2-in-3 chance of receiving the investigational medication. The safety and efficacy of the investigational medication for HDFN have not yet been established.



**Study Site Locations:** The AZALEA study is a global clinical trial, currently being conducted at 55 institutions in 17 countries, and is expected to expand to additional sites through 2026. The current list of open sites in the U.S. (as of September 2025) is included below. Please refer to [J&J Clinical Trials](#) for a full, up-to-date list of sites across the world. The team at each study site is led by a maternal fetal medicine (MFM) specialist who serves as the Principal Investigator (PI).



**Interested in learning more?** If you think the AZALEA study may be right for you:

- Talk to your OB/GYN or MFM
- Visit <https://azaleatrial.com/> for more information about the study and participating sites in the U.S. The website features an online pre-screener that you can complete to get connected to the site closest to you. You're encouraged to complete the pre-screener even if you aren't currently pregnant but are planning a pregnancy.
- Visit [J&J Clinical Trials](#) if you're located outside the U.S. and want to get connected to the study site closest to you.

Participation in AZALEA is voluntary. Learning more does not mean you're required to join. Even if you begin the trial, you can change your mind at any point. The trial doctor will discuss your care options with you if you decide to withdraw.