

Safety of Efgartigimod in Pregnancy: Bench-to-Bedside

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KEY TAKEAWAYS

Nonclinical data showed an expected transient IgG reduction and no adverse effects on fetal development or fertility following maternal efgartigimod treatment

Patient advocacy helped identify patient-relevant priorities and guide usage of ARGOVIA data

The ARGOVIA process collected the largest human pregnancy data for efgartigimod so far; data evaluation to date is reassuring

The findings from this bench-to-bedside approach will support more informed risk-benefit decisions on MG therapies in pregnancy, where treatment options remain limited and unmet need is high

BACKGROUND

- MG commonly affects women during their reproductive years, making pregnancy management and maternal-fetal outcomes important clinical considerations¹⁻³
- A meta-analysis of MG pregnancies found⁴:
 - A 34% risk of disease exacerbation during pregnancy
 - A 6.4% risk of myasthenic crisis during pregnancy, rising to an 8.2% risk during the postpartum period
 - A 13% incidence risk of transient neonatal myasthenia gravis in newborns
- A lack of clinical and real-world data from gestational exposure to efgartigimod can lead to treatment discontinuation or use of older therapies with high side-effect burden during pregnancy³
- Improved clinical safety data collection methods may support more informed risk-benefit decision-making on MG treatment during pregnancy

OBJECTIVE

Present a cross-functional approach addressing the safety of efgartigimod treatment in pregnancy for mother and child

METHODS

FIGURE 1 The Bench-to-Bedside Principle for Assessing Efgartigimod Safety in Pregnancy

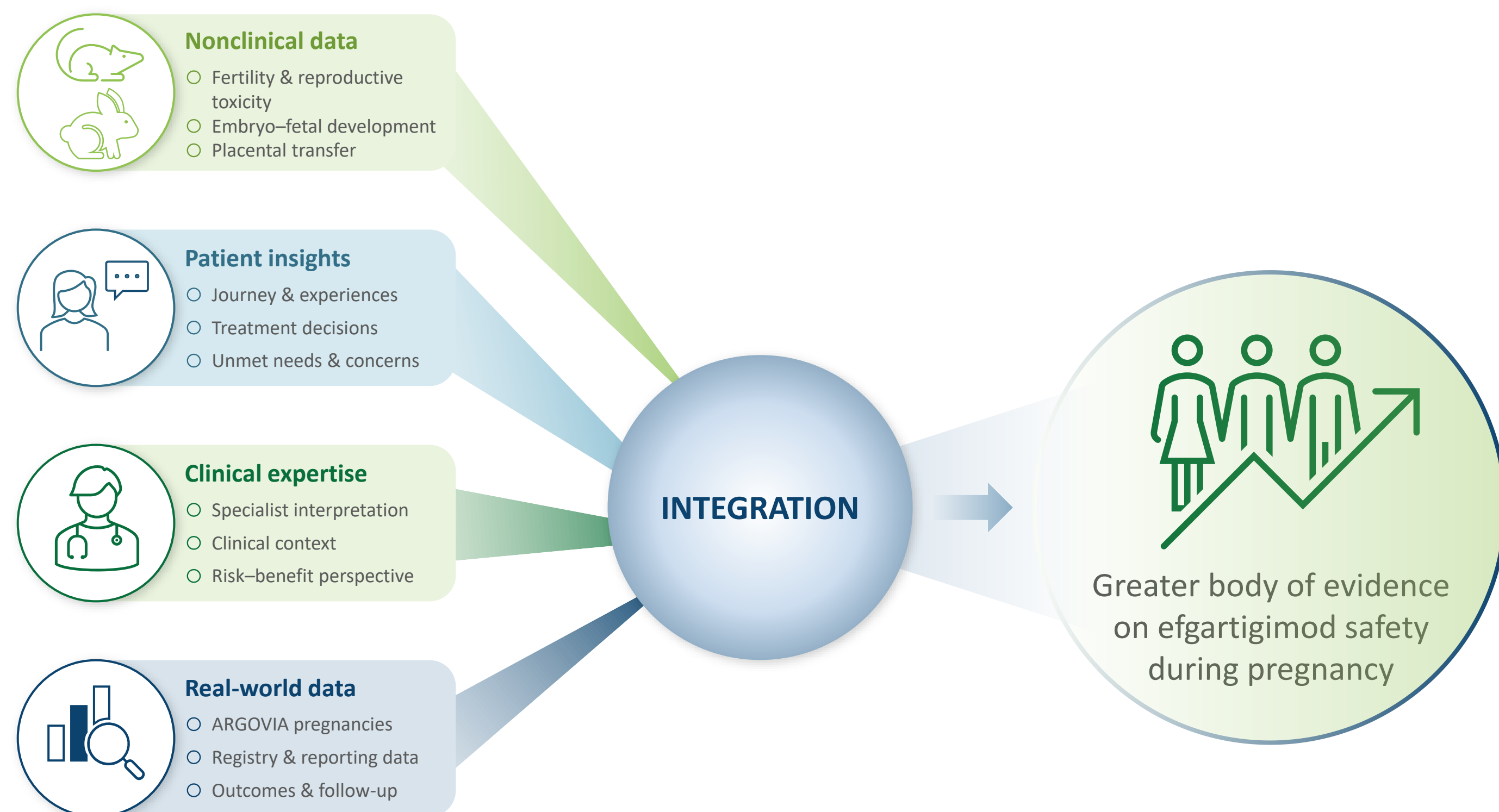
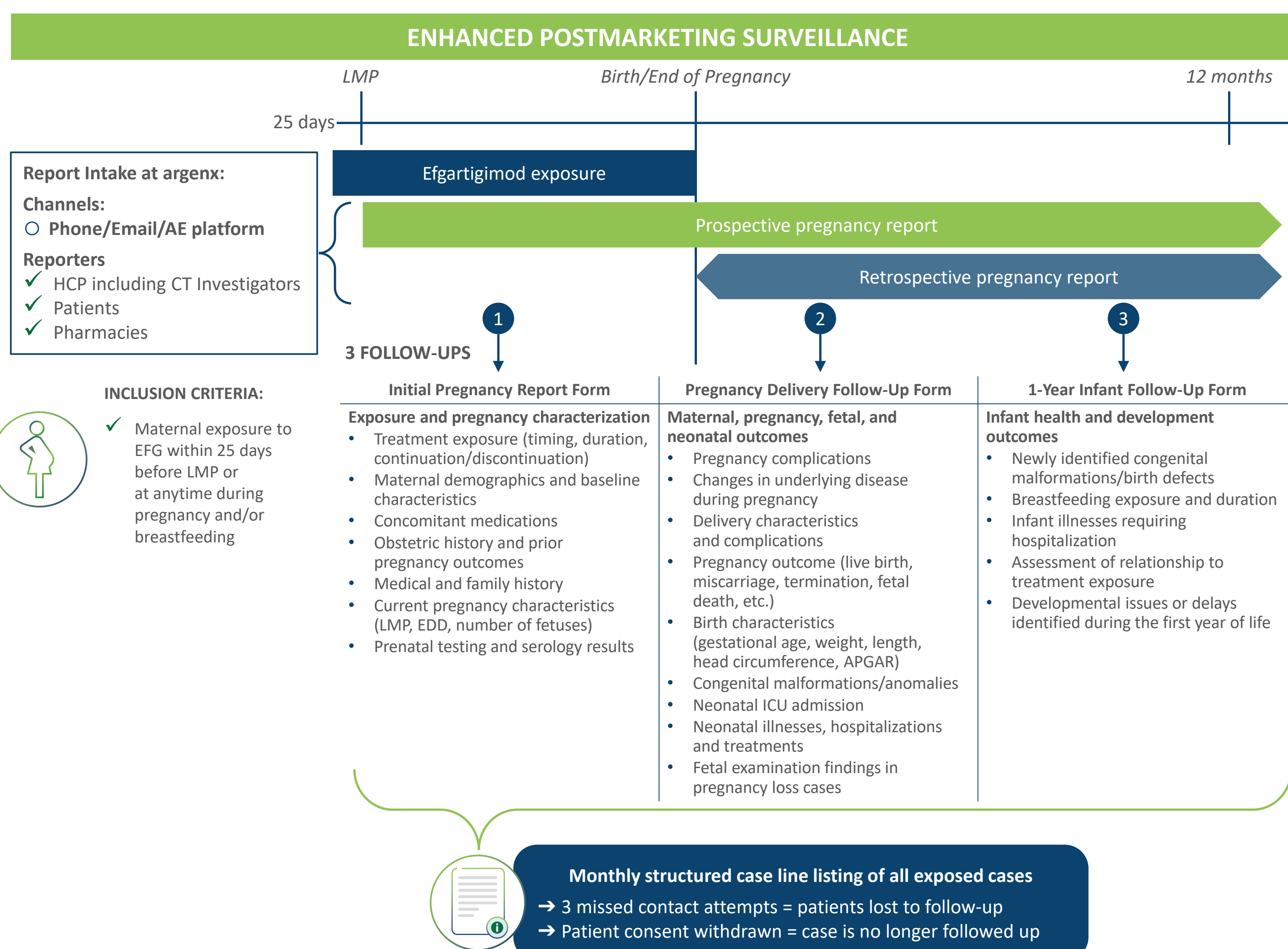


FIGURE 2 The ARGOVIA Process Enables Real-Time Data Collection



RESULTS

TABLE 1 Nonclinical Studies Did Not Identify Reproductive or Developmental Toxicity Concerns and Demonstrated Minimal Placental Transfer After Efgartigimod Treatment

Study	Animal model	Translational FAQ	Key results
Fertility and Early Embryonic Development		Does the drug affect the ability to become pregnant or the very early stages of pregnancy?	Together, these studies demonstrated that efgartigimod administered up to 100 mg/kg/day resulted in: ✓ No treatment related maternal mortality or morbidity ✓ Minimal placental transfer of efgartigimod during pregnancy in rats ✓ Greater reduction in total IgG levels in pregnant dams compared to controls ✓ Reduced placental transfer of total IgG during pregnancy in rats ✓ No effect on number, viability, malformations and variations, and weight of embryos/fetuses ✓ No effect on fertility indices and gestation index, pre-coital time, gestation length and maternal care, pup survival, growth, sexual maturation, learning and memory, and production of F2 generation
Embryo-Fetal Development		Does the drug harm the embryo/fetus while it is developing in the womb across species?	
Placental Transfer of Efgartigimod Administered by Intravenous Route		Does the drug reach the fetus during pregnancy? Does the drug change how antibodies pass from the dam to the fetus?	
Pre- and Postnatal Development Toxicity		Does the drug affect the offspring after birth, including growth, development, and future fertility?	

FIGURE 3 A Patient Advocacy Panel Highlighted Key Priorities in MG Pregnancy Safety

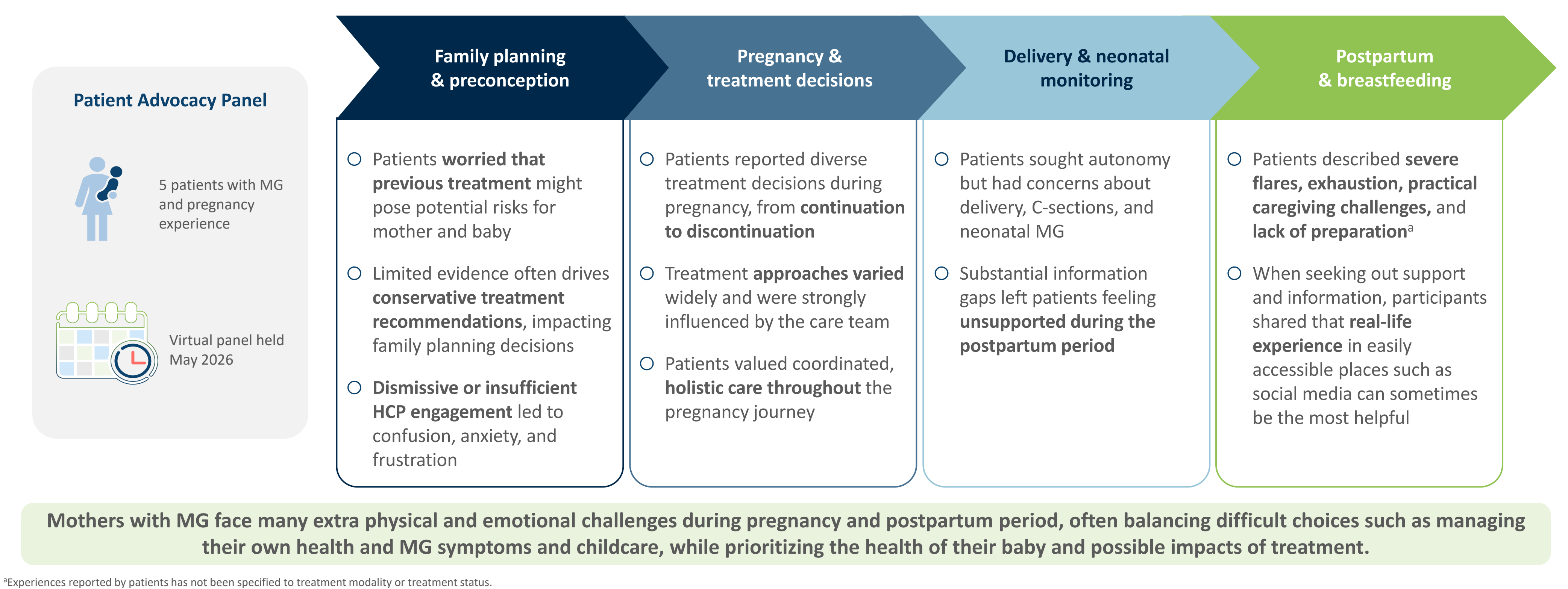
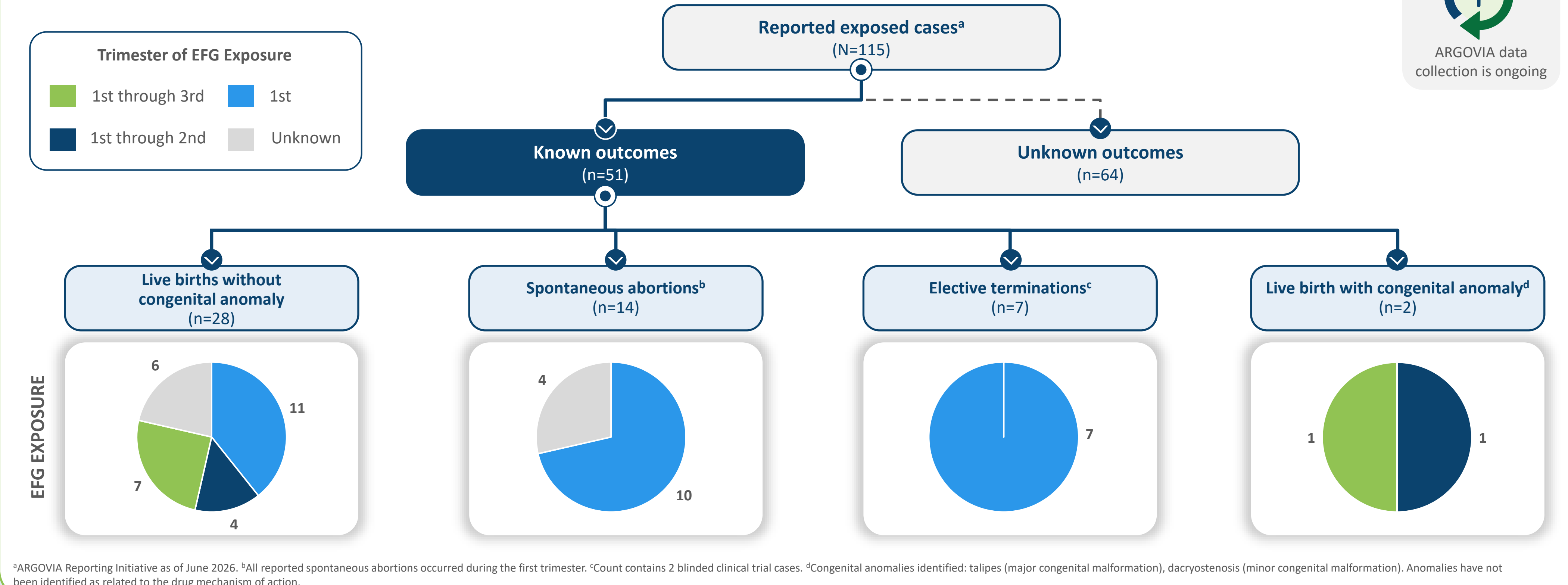


FIGURE 4 The Majority of Efgartigimod-Exposed Pregnancies With Known Outcomes Reported via ARGOVIA Resulted in Live Births



CALL TO ACTION

Closing the evidence gaps in MG pregnancy safety as fast and reliably as possible may allow for more and better treatment options for physicians and patients

Help advance pregnancy safety evidence. Enroll your patients today at vygartpregnancy.com

Please scan this QR code to access pregnancy reporting contact information

ABBREVIATIONS

AE, adverse event; APGAR, Apgar score (appearance, pulse, grimace, activity, respiration); ARGOVIA, Argenx Real-world generation of pregnancy and neonatal Outcomes through pharmacovigilance, Insights and Analysis; CT, clinical trial; EDD, estimated due date; EFG, efgartigimod; HCP, healthcare professional; ICU, intensive care unit; IgG, immunoglobulin G; LMP, last menstrual period; MG, myasthenia gravis.

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