EPCORE™ PEDS-1
M20-429

Don't face the journey with lymphoma *alone.*

The journey for your child, teen, or young adult with non-Hodgkin lymphoma shouldn't be a lonely one—join a growing community of people seeking answers through clinical research. Consider the EPCORE PEDS-1 Study for your loved one today.

The EPCORE PEDS-1 Clinical Research Study

The EPCORE PEDS-1 Study is evaluating the safety, tolerability, and pharmacokinetics (what the body does to the drug) of an investigational drug for children, teens, and young adults with aggressive forms of mature B-cell non-Hodgkin lymphoma (NHL) that is either relapsed or refractory.

- Relapsed: Their lymphoma previously responded to therapy but progressed 6 months or later after completing therapy
- Refractory: Their lymphoma either progressed during therapy, did not respond to prior therapy, or progressed within 6 months after completing therapy (including maintenance therapy)

Your child, teen, or young adult may be able to take part in the EPCORE PEDS-1 Study if they:

- Were at least 1 and under 18 years old at the time of primary diagnosis
  - Those with relapsed or refractory Burkitt's or Burkitt-like lymphoma/leukemia who are up to 25 years old may also be eligible
- Have a diagnosis of one of the following relapsed or refractory mature B-cell NHLs:
  - Diffuse large B-cell lymphoma (DLBCL)
  - Burkitt's or Burkitt-like lymphoma/leukemia
  - Other aggressive mature B-cell lymphomas
- Have received at least 2 lines of systemic therapy to treat their lymphoma (systemic therapy is treatment that travels through their bloodstream)

If you and your child, teen, or young adult are interested in participating, the study doctor and staff will review additional eligibility criteria with you.

This investigational drug being studied in mature B-cell NHL patients is under clinical development and is not approved for use by regulatory health authorities. Safety and effectiveness are under evaluation.

FAQs

What's involved with participation in the EPCORE PEDS-1 Study?

In this study, the investigational drug will be studied as a single-drug treatment, or monotherapy. The investigational drug dosing will be based on weight. There is no placebo in this study, which means all participants will receive the actual investigational drug for their study treatment.

This study is divided into the following parts:

- Screening
  - Up to 28 days, and may be completed in 1 or more study visits
  - Determines if your child can be in the study
- Study Treatment Period
  - Length of time on study treatment varies based on the response to the study drug
  - The study drug is given in 28-day cycles
  - Study treatment visits are about once a week for the first 3 cycles, then every other week for 6 cycles, then about once a month for up to 2 years from enrollment
- Post-Study Treatment Follow-Up
  - Participants will have a safety follow-up within about 120 days of their last study treatment, and then additional follow-up visits at prespecified time points until the study ends

Total study duration will depend on each participant's response to the study drug. Participants may leave the study at any time without further explanation.

Does participating in this study cost anything?

If your child qualifies for and you both agree to participate in the study, you will not have to pay for the investigational drug. In addition, reimbursement for study-related travel expenses may be available.

If prequalified, what can I expect on my first visit to the study clinic?

This initial appointment is an opportunity for you and your child to:

- **Ask any important questions you may have.** These can be any questions you may have about this study or clinical research in general.
- **Determine if the EPCORE PEDS-1 Study may be right for your family.** You will speak with a study coordinator and learn more about the study. The study coordinator will ask you about your child's health history to determine if they are eligible for the study. If they are eligible, you both will be given the opportunity to decide if participation is right. If you and your child agree to take part, you will be asked to review and sign a consent form for study participation. You and your child can also leave the study at any time. Once you have signed the study consent form, the research staff will perform a series of tests to determine if your child is right for the study, and if the study is right for them.

FAQs

What if my child's condition worsens or they have side effects?

You should make sure to inform your child's doctor of any new symptoms they experience while participating in the study. If your child experiences a worsening of their disease at any time during the study, please let the study doctor and staff know.

Where are the study clinics located?

There are study clinics located throughout the world. Find a location near you at: **[Study Locations URL]**.