

#### The RSVPEDs Study: Working to Advance Treatment Options for Infants and Toddlers infected with Respiratory Syncytial Virus (RSV)

The RSVPEDs Study is evaluating an oral investigational medicine designed to potentially treat RSV infections, including reducing the duration and severity of the illness. If your child is between the ages of 28 days and 36 months, has RSV infection or symptoms of RSV infection, and you want to determine if this clinical study may be an option for your child, please speak with a member of our study team.

### What is a clinical study?

Clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment is safe and effective in people. (Definition from National Institutes of Health website, www.nia.nih.gov)

Clinical studies play an important role in the development of new medical treatments. By choosing to enroll your child in the RSVPEDs Study, you are helping us better understand the investigational medicine and how it can potentially improve the treatment of RSV infection.

Participation in a clinical study is completely voluntary. Your decision to have your child participate or not participate will have no effect on the medical care he/she receives, either now or in the future. If your child is eligible and you choose to have him/her take part, you may withdraw them from the clinical study at any time, and for any reason.

To learn more about clinical studies and this RSVPEDs study please visit https://revpeds.longboat.com to watch a short video (password: rsvpedsCNI#) or visit the study website at:

#### www.RSVPEDs-Study.com





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A Clinical Study for Infants and Toddlers (aged 28 days to 36 months) Infected with Respiratory Syncytial Virus (RSV)



### Taking a Closer Look at Respiratory Syncytial Virus (RSV)

If you are the parent of an infant or toddler up to 3 years of age, you may already be familiar with RSV infection, a common and very contagious virus that infects the respiratory tract of most infants and young children before their second birthday. RSV infection is transmitted when an infected person coughs or sneezes, or through direct contact with contaminated surfaces, and is easily spread to children. The common symptoms of RSV infection include:

- o Cough
- Runny nose
- Nasal congestion
- o Fever
- Rapid breathing
- o Shortness of breath
- Wheezing
- Dehydration

While some cases of RSV infection cause nothing more than cold symptoms, severe cases can result in significant respiratory problems including difficulty breathing. Such cases may require hospitalization and/or more aggressive treatments.

#### If your child has been infected with RSV, here are a few more important things you should know:

- RSV infection is a common respiratory virus that usually results in mild, cold-like symptoms
- While most children recover in a few days, more serious symptoms can quickly develop, especially in infants and young children
- Supportive care for children with RSV infection includes frequent monitoring of clinical status and provision of fluid and respiratory support as necessary
- o The standard-of-care treatment for RSV infection may include uses of saline nasal drops, a cool mist vaporizer, and non-aspirin fever-reducers such as acetaminophen
- o Currently, there are no approved treatments for RSV infection

#### What is the RSVPEDs Study?

Researchers are working to find a treatment for RSV infection, and the purpose of this study is to see if an experimental medicine, EDP-938, will help. The RSVPEDs Study will evaluate how safe and effective EDP-938 is in treating children with RSV infection and determine the dose of EDP-938 that works best. EDP-938 has been tested in healthy adults and has shown it was well tolerated.

#### What does participation look like?

If your child is eligible to participate, they will have up to 7 visits with the study doctor and be enrolled in the study for 29 days. During this time, your child will:

- o Take the study medicine for 5 days
- o Receive the standard-of-care treatment for RSV infection
- o Complete all study procedures and tests
- o Be closely monitored by both their doctor and our team of medical professionals until your child completes the study

# Why consider enrolling your child in the RSVPEDs Study?

While it is hoped that your child will benefit from EDP-938, there is no guarantee that your child will receive any benefit from taking part in this study. Your child's condition may improve, but it could remain the same, or could get worse. Information obtained from the study may help in the development of better treatments for RSV infection in children.

# Your child may be eligible to participate if they are:

- o Between the ages of 28 days and 36 months
- o Infected with respiratory syncytial virus (RSV)
- o Experiencing symptoms of RSV infection
- o Either hospitalized or not hospitalized for RSV infection

### What is included in study participation?

There are no costs associated with participating in this clinical study. The following items will be provided to you and your child free of charge:

- o The study medicine
- o All study-related visits, procedures, and tests
- o Reimbursements for any reasonable expenses incurred by taking part in the study
  - This may include:
  - o Food
  - o Travel to and from study visits
  - o Parking for study visits

