GE-045-401 – A Phase 4 Multicentre Study to Evaluate Safety and Efficacy of Sonazoid™ for Contrast-Enhanced Ultrasound Liver Imaging in Paediatric Patients.

Your child is invited to take part in a research study of a diagnostic imaging agent called Sonazoid™. This leaflet will give you some information about the study. If you want to learn more, you can ask the research doctor or nurse or read the parental information and consent form which has more details.

Diagnostic imaging agents are medicines given to patients before or during an imaging procedure to help make the pictures clearer for the doctor. This research study may help to identify safer and/or more effective ways of diagnosing and treating children who need ultrasound scans of their liver.

# What is the goal of this research study?

The purpose of this study is to see if ultrasound images with Sonazoid<sup>™</sup> can be used to diagnose and tell the difference between different types of untreated masses in the livers of patients under the age of 18. Also, to see if Sonazoid<sup>™</sup>, which has shown to be safe in adults, is also safe for younger patients under the age of 18 when carrying out ultrasound of the liver.

# Why participate?

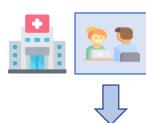
Taking part in research means that you will be making an important contribution to the future diagnosis and treatment of patients and that could include yourself, your child and/or your friends and family. This is true even if the medicine being studied is not as good as the researchers hoped. We learn from all research.

#### INSERT INSTITUTION HEADER OR LOGO

Insert site Contact
Information here

Your doctor/nurse can provide more information about how we can support with transport and costs to help you to attend visits.

### **GE-045-401 Study- Patient Journey**

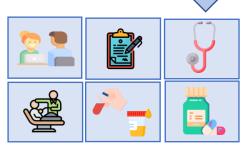


(2) If you and willingness t

(2) If you and your child confirm interest and willingness to participate – you are invited to attend a screening visit

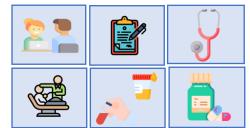
study doctor, family and/or friends.

(1) Research doctor or nurse approaches you about this study for your child. You and your child are given information about the study and can discuss with your



Up to 14 days between Screening and Imaging visits (on the same day <u>if</u> hospital has time)

- (3) You and your child attend a screening visit:
  - Sign consent/assent form
  - Medical history and review of medications
  - · Vital signs
  - Physical exam
  - Blood & urine samples
  - Pregnancy test (if applicable)



(4) You and your child attend an imaging visit:

#### Before imaging:

- · Review of medications
- Vital signs
- Physical exam
- Blood & urine samples
- Pregnancy test (if applicable)

### Imaging:

- Ultrasound before Sonazoid™
- Injection with Sonazoid™
- Injection site monitoring
- 2 x Ultrasounds after Sonazoid™ (one straight away and one after 20 minutes)

#### After Imaging:

- Injection site monitoring
- Vital Signs
- Physical exam
- Blood & urine samples





- (5) You will receive a telephone call 24 hours after your child's Sonazoid™ injection and again at 72 hours:
  - Review of medications
  - Well-being of your child will be assessed

End of Study