CF STORM
CLEARING THE AIR

CF STORM Child (6-11 years) Information Sheet

What is a study?

- A research study is what doctors do when they want to learn about something, or find out something new.

What is the CF STORM study?

- You have started taking a new medicine (Kaftrio™) and we would like to learn if you still need to take some of your other medicines (nebulisers) at the same time.
- Your part in the study would last for about a year and we will ask questions to find out how you are getting on during that year.

Why have I been invited?

- Because you take medicines (nebulisers) for your Cystic Fibrosis and have been taking a new medicine (Kaftrio™).
- We are inviting other children and adults from all over the country who have Cystic Fibrosis like you to take part in the study.

If I take part, what do I have to do?

- You will be asked to write your name on a phone or an iPad or a computer, this tells us you understand what the study is for and what will happen. The grown up who looks after you will also have to sign a form to say they are happy for you to take part.
- If you choose to take part your nurse or doctor will see you during your usual appointments.
- It is very important that you tell your mum, dad or the grown up looking after you and your doctor if you are feeling poorly.
- During the study the grown up who looks after you will be sent some questions for you to answer. It's not like a quiz with a right or wrong answer. These questions help us understand how you are generally feeling. You will be asked these same questions four times over the year to see if anything changes. A different set of questions at the start and end of the study find out how you are feeling about your Cystic Fibrosis.

How will my medicine change if I take part?

- During the study you will be asked to either:
  1. carry on taking all your normal medicines (including your nebulisers)
  2. **or** stop taking one or two or your normal nebulisers (but keep taking your other CF medicines)
- A computer decides if you will be asked to do 1 or 2. The grown up who normally looks after you will be told if your medicines should change.

Do I have to take part?

- No, you don't. If you don't want to take part nobody will mind.
- If you change your mind, that's OK as well.

What are the good or bad things about taking part?

- You may get a chance to do one less nebuliser each day which is good. However, sometimes if you stop taking some of your medicines you might feel less well. But the grown up who looks after you will speak to your doctor if this happens and they will look after you.

Who will my information be shared with?

- Your information will include the answers to the questions you're asked as part of the study and how your health has been. We will ensure your information is correct and that it is shared in a way that only those who need it will have access to it. It won't include your name, but your information may be helpful for other studies at universities, hospitals or companies in this country or abroad.

Who is running the CF STORM study?

- The study is being run in your hospital with your CF Team.
- It is organised by Alder Hey Children's Hospital NHS Foundation Trust ,the University of Liverpool and University of East Anglia. The UK CF Registry will collect all of your information.
- The money needed to set up and run this study has been provided by National Institute for Health Research- Health Technology Assessment programme.

What do I do if I have any questions?

- Your mum, dad or the grown up who looks after you have been given lots of information, but you can also talk to the nurse or doctor who look after you to find out anything you want to know.
- You can ask questions before you decide to join the study, any time during the year you are taking part and afterwards too.
- You can also look at our website: **www.cfstorm.org.uk**

Thank you for reading about this study!