

"We're Almost There"

**48 / 52 patients successfully randomised**

- In response to COVID-19 pandemic, Isaiah recruitment was paused in March 2020
- The first Isaiah site was re-opened in May 2020

SITE NAME	STATUS AFTER THE COVID-19 OUTBREAK
Imperial	Re-opened
Kings	Re-opened
Oxford	Not yet
Glasgow GRI	Re-opened
Royal Free	Re-opened
Royal Liverpool	Not yet
Aintree	Re-opened
Plymouth	Re-opened
Nottingham	Re-opened
Newcastle	Re-opened
Bristol	Not yet
Chelsea & West	Re-opened
Leeds	Not yet
Southampton	Re-opened
St Georges	Re-opened

- Study recruitment has been extended to 31<sup>st</sup> of December 2020 as per Non-Substantial Amendment no 1
- Next DMEC/TSC meetings are due in October and November 2020, respectively
- Current Isaiah Protocol is v4.0 dated 13.08.19



### LABELING ISAIAH SAMPLES

**The shipments of the Isaiah research samples will start soon, therefore a few important reminders:**

- The Isaiah research samples should be labelled with Isaiah specific labels, received at SIV
- For biopsy samples (snap frozen tissue and histology samples), please use the green labels
- The label should contain the Subject ID, Sample type, Time and date of sample collection, Visit date
- No patient sensitive information should be ever entered!!!
- The local biopsy reports are not required
- Only appropriate labelled samples can be accepted

### ISAIAH SAFETY REPORTS IMPORTANT REMINDER OF DEFINITIONS

- So far, we have 38 SAEs on Isaiah
- As a reminder, the 'Causality' is the relationship of the AE to the study IMP and is graded by the PI responsible for the care of the participants (for further details please see protocol v4.0, page 36 and Isaiah safety reporting manual)
- When considering causality take into account time since IMP administration and other co-morbidities
- Expectedness should be assigned by referring to SmPC
- Current Isaiah SmPC is from March 2020

#### Assessing AEs/ARs

	Serious
<b>Seriousness</b>	<ol style="list-style-type: none"> <li>1. Results in death</li> <li>2. Life threatening</li> <li>3. Requires hospitalisation (24h or more)</li> <li>4. Results in persistent or significant incapacity</li> <li>5. Other/medically significant</li> </ol>
<b>Causality</b>	<ol style="list-style-type: none"> <li>1. Not related</li> <li>2. Unlikely related</li> <li>3. Possibly</li> <li>4. Probably</li> <li>5. Definitely</li> </ol>
<b>Expectedness</b>	<ol style="list-style-type: none"> <li>1. Expected – listed in the SmPC</li> <li>2. Unexpected – not listed in the SmPC</li> </ol>

# Isaiah Research Samples Labelling

1.

## Use Isaiah Specific labels

### White labels:

ISAIAH CK Serum

Patient ID: \_\_\_\_\_

Day: \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

Time: \_\_\_\_:\_\_\_\_

Or

### Green labels:

ISAIAH Biopsy Histology

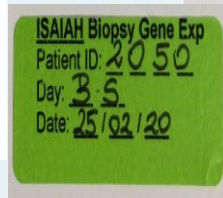
Patient ID: \_\_\_\_\_

Day: \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

2.

## Always pre-label the vial



3.

## Write only

- Patient ID
- Sample type
- Visit Day
- Date/Time

4.

## Histology samples

- Request block and slides from histology lab
- Masked all the identifiable patient data written on blocks and slides
- **Label the block and slides** using the green labels
- **DO NOT SEND HISTOLOGY REPORT**

READ AND UNDERSTOOD CONTENTS OF NEWSLETTER

PI NAME:

.....

PI SIGNATURE:

.....

DATE

.....