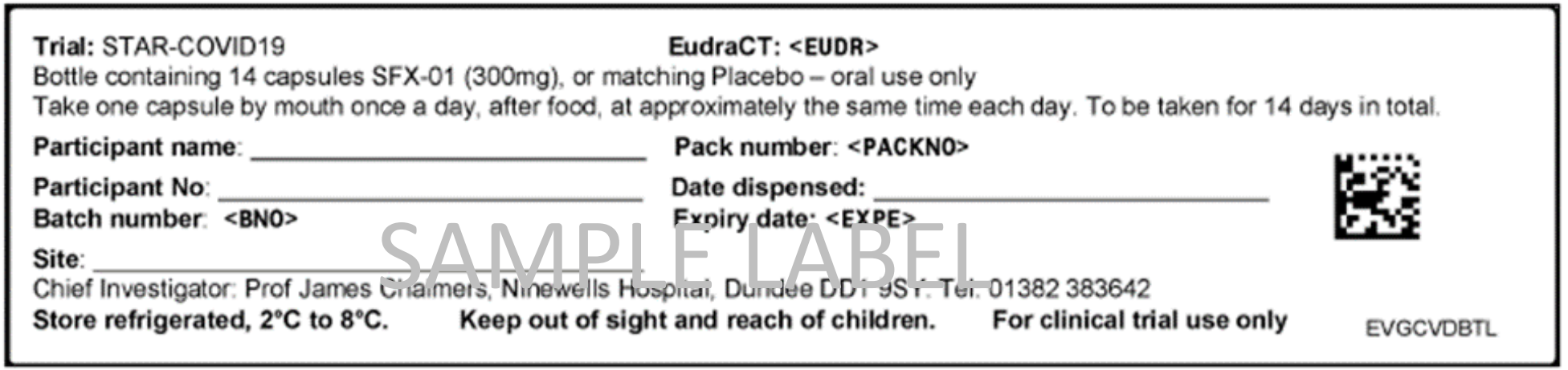
SFX-01 **t**reatment for **Acute Respiratory Infections** (STAR-Covid19)

IMP Management

IMP



- SFX-01 (sulforaphane) or placebo
- Supplied by Evgen Pharma PLC, distributed by ALMAC
- 300mg capsules supplied in bottles of 14 capsules labelled as above

Dosing

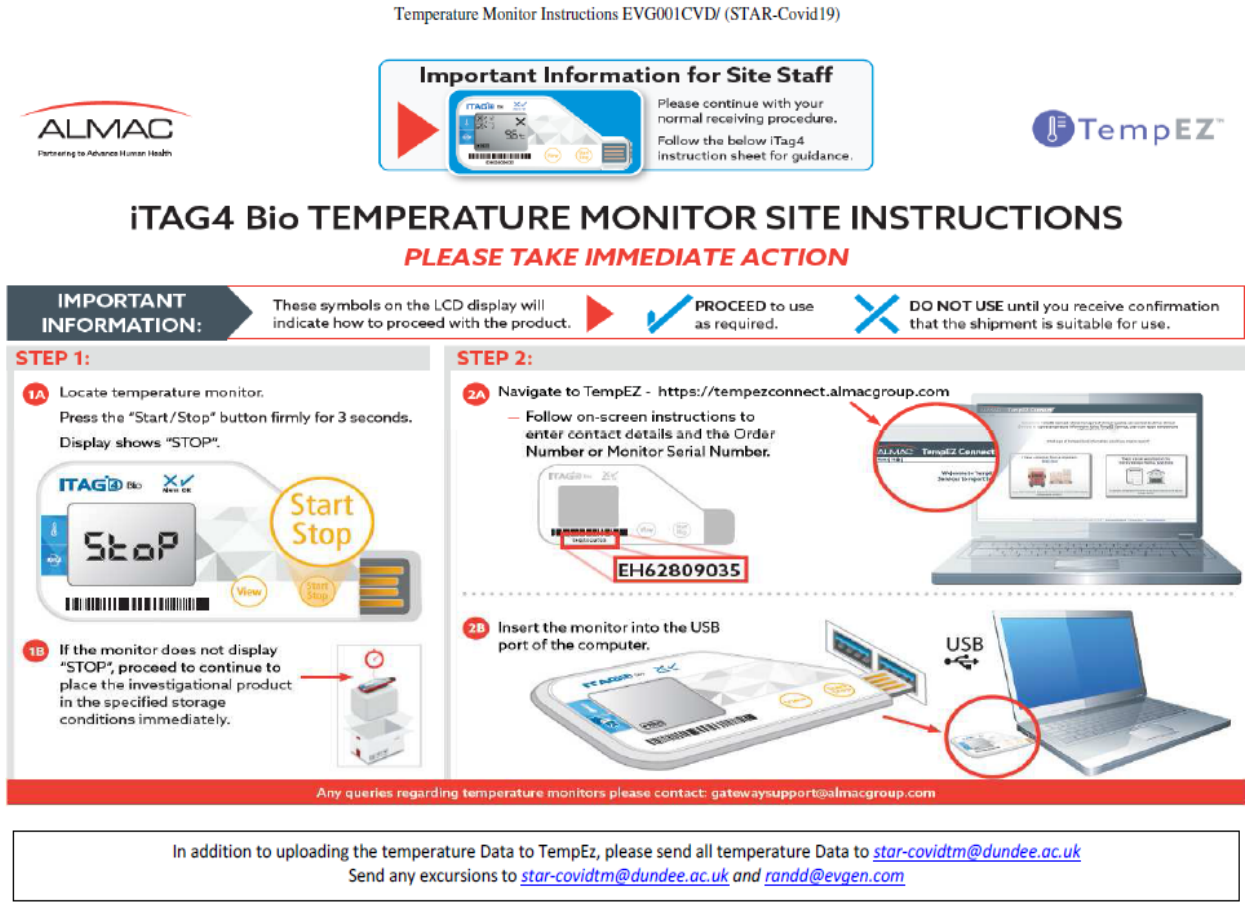
- One capsule daily for 14 days
- To be taken up to 2 hours after food at approximately the same time each day
- Missed dose:
  - Give within 12 hours, record as late dosing
  - If over 12 hours wait for next dose and record as missed dose
- If naso-gastric tube (NGT): dissolve in 20ml water, push through NGT using a syringe, flush with 10ml of water (or saline), clamp NGT for 30 mins
- If discharged from hospital, remaining IMP taken home. Advice given to patient to store in fridge

IMP supply 1

- Initial supply to site will be 10 bottles
- ALMAC will supply IMP to Clinical Trial Pharmacy (CTP)
- TCTU trial manager will manage stock – if levels are causing concern please contact them

- Each shipment will come with a packing list
  - CTP should check the received stock against the packing list, sign, scan and email to star-covidTM@dundee.ac.uk

IMP supply 2


Temperature Monitor Instructions EVG001CVD/ (STAR-Covid19)

ALMAC

Important Information for Site Staff

Please continue with your normal receiving procedure.

Follow the below iTag4 instruction sheet for guidance.

TempEZ

iTAG4 Bio TEMPERATURE MONITOR SITE INSTRUCTIONS

PLEASE TAKE IMMEDIATE ACTION

IMPORTANT INFORMATION: These symbols on the LCD display will indicate how to proceed with the product. PROCEED to use as required. DO NOT USE until you receive confirmation that the shipment is suitable for use.

STEP 1:

1A Locate temperature monitor.
Press the "Start/Stop" button firmly for 3 seconds.
Display shows "STOP".

1B If the monitor does not display "STOP", proceed to continue to place the investigational product in the specified storage conditions immediately.

STEP 2:

2A Navigate to TempEZ - https://tempezconnect.almacgroup.com
– Follow on-screen instructions to enter contact details and the Order Number or Monitor Serial Number.

EH62809035

2B Insert the monitor into the USB port of the computer.

USB

Any queries regarding temperature monitors please contact: gatewaysupport@almacgroup.com

In addition to uploading the temperature Data to TempEz, please send all temperature Data to star-covidtm@dundee.ac.uk
Send any excursions to star-covidtm@dundee.ac.uk and randd@evgen.com

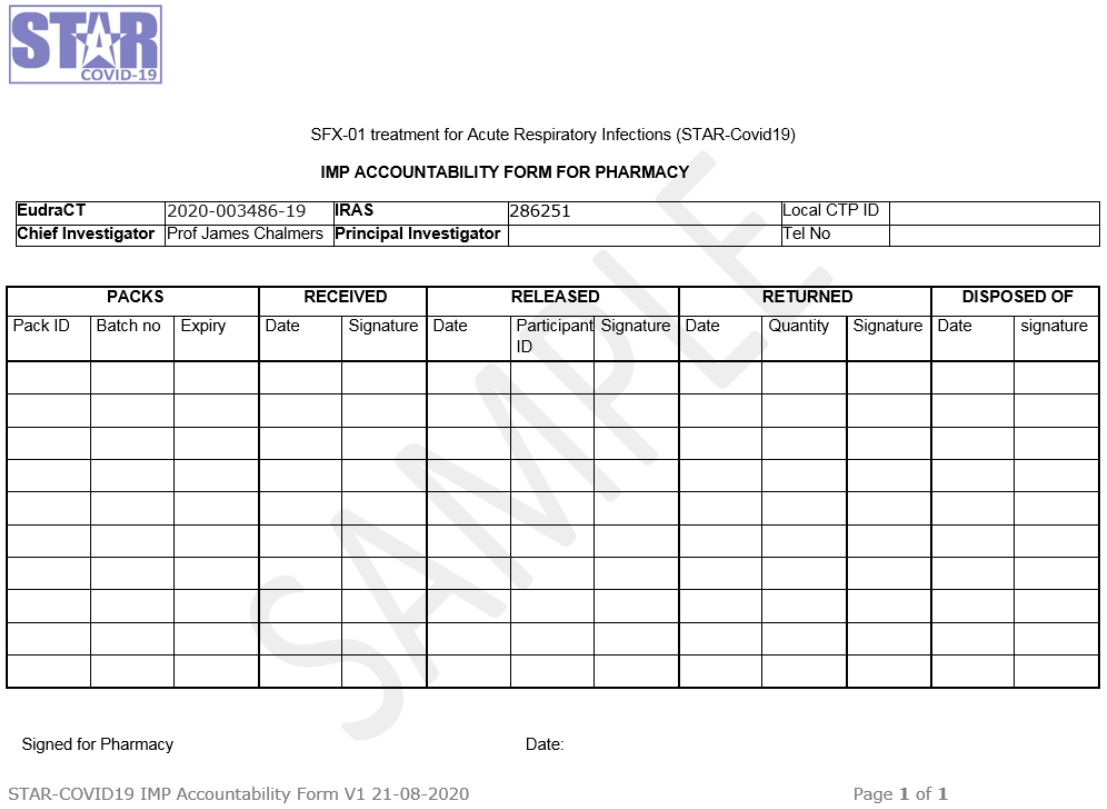
- Each shipment will also come with a temperature monitor (iTAG) together with iTAG instructions
- iTAG should be connected to a computer and data uploaded. Data should be emailed to star-covidTM@dundee.ac.uk
- If the tag shows that an excursion has occurred please contact star-covidTM@dundee.ac.uk and randd@evgen.com. **IMP must be quarantined** until TCTU confirm to CTP either that the IMP can be removed from quarantine and prescribed as required, or that the IMP must be returned/destroyed and further stock ordered

IMP storage

- All IMP to be stored securely between 2°C and 8°C
- Daily temperature log should be kept whilst IMP is in pharmacy:
  - Log must be retained for audit
  - Pharmacy Site file (PSF) file note to detail location of log
- If IMP is exposed to temperatures below 2°C or above 8°C
  - IMP must be quarantined; clearly marked as being in quarantine and stored separately
  - CTP must inform star-covidTM@dundee.ac.uk and randd@evgen.com, including temperature logs from the preceding 4 weeks
- Following discussion with Evgen and Sponsor, the trial manager will inform site CTP what action is necessary

IMP accountability

- IMP accountability records will be maintained by each site
- IMP accountability forms will be provided and held in the PSF



SFX-01 treatment for Acute Respiratory Infections (STAR-Covid19)

IMP ACCOUNTABILITY FORM FOR PHARMACY

EudraCT	2020-003486-19	**IRAS**	286251	Local CTP ID	
Chief Investigator	Prof James Chalmers	**Principal Investigator**		Tel No	

PACKS			RECEIVED		RELEASED			RETURNED			DISPOSED OF	
Pack ID	Batch no	Expiry	Date	Signature	Date	Participant ID	Signature	Date	Quantity	Signature	Date	signature

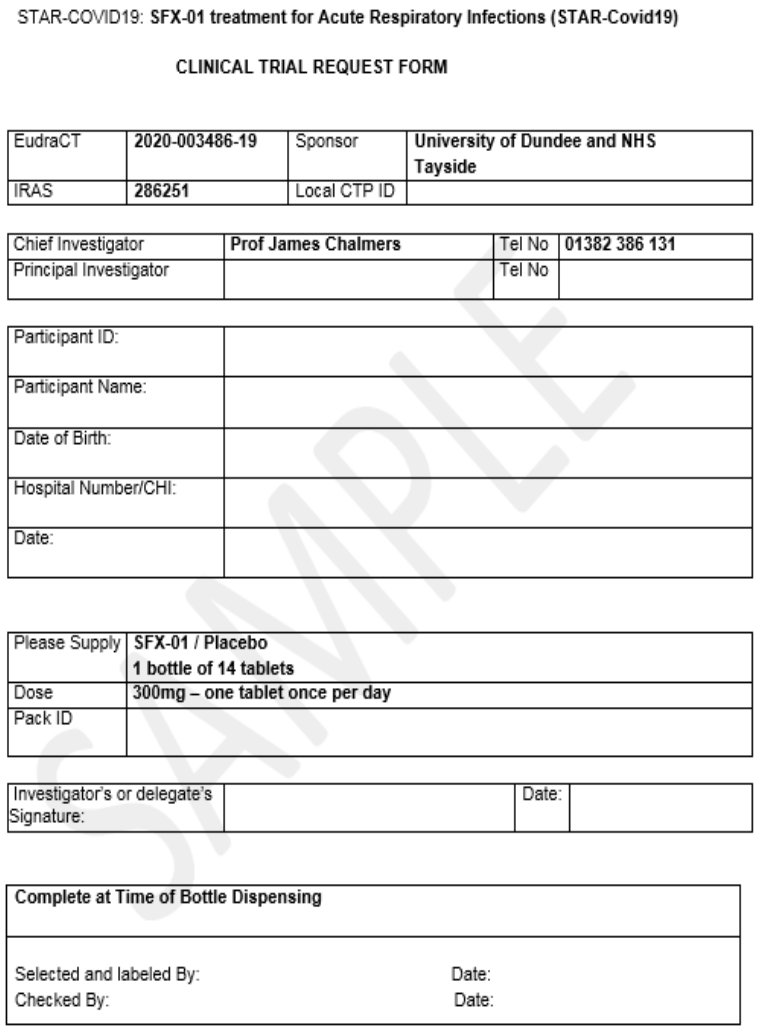
Signed for Pharmacy Date:

STAR-COVID19 IMP Accountability Form V1 21-08-2020 Page 1 of 1

SAMPLE

IMP release following randomisation 1

- When a participant is randomised, TRuST (Tayside Randomisation System) will generate a pack ID to be issued to that participant
  - This information will automatically be emailed to CTP
  - The research nurse will take a printed copy of the allocation email generated by TRuST and a completed STAR-COVID19 Clinical Trial Request Form to CTP.



STAR-COVID19: **SFX-01 treatment for Acute Respiratory Infections (STAR-Covid19)**

CLINICAL TRIAL REQUEST FORM

EudraCT	**2020-003486-19**	Sponsor	**University of Dundee and NHS Tayside**
IRAS	**286251**	Local CTP ID	

Chief Investigator	**Prof James Chalmers**	Tel No	**01382 386 131**
Principal Investigator		Tel No	

Participant ID:	
Participant Name:	
Date of Birth:	
Hospital Number/CHI:	
Date:	

Please Supply	**SFX-01 / Placebo** **1 bottle of 14 tablets**		
Dose	**300mg – one tablet once per day**		
Pack ID			

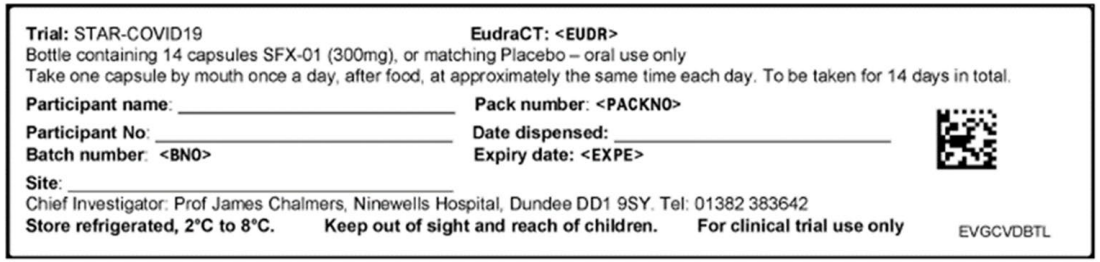
Investigator's or delegate's Signature:		Date:	

Complete at Time of Bottle Dispensing
Selected and labeled By: Date: Checked By: Date:

SAMPLE

IMP release following randomisation 2

- Clinical Trial Pharmacy/delegated staff will verify that the pack ID on the bottle issued matches the number on the Request form
- At time of release Clinical Trial Pharmacy/delegated staff adds to the IMP bottle
  - Participant name
  - Participant number
  - Site name
  - Date of dispensing



- The STAR-COVID19 Clinical Trial Request form will be filed in the PSF

IMP release following randomisation 3

- IMP is released in bottles of 14 capsules
- Participants receive 1 capsule per day for 14 days
- IMP bottle must be securely stored in the ward fridge as local practice:
  - IMP should be prescribed on drug chart/equivalent as per local practice
  - IMP should be given by clinical staff once daily
  - If participant is moved IMP should accompany patient
- Any allocated and in-use IMP inadvertently left at room temp for **up to 48 hours** may be returned to the fridge and safely given to participant
- Any allocated and in-use IMP left at room temperature for **more than 48 hours** should be returned to pharmacy and a replacement bottle requested from the trial management team (star-covidtm@dundee.ac.uk)

IMP returns

- Participants discharged from hospital will be provided with the remainder of the IMP and instructions to complete 14 days treatment:
  - Participants will be given a stamped addressed envelope to post back returns/empty bottles
  - Participant diary will detail instructions for participants
  - Returns should be handles as per local infection control policy
- IMP returned to CTP should be counted and entered on Accountability Log
- IMP will be disposed of following local disposal policy and recorded on Disposal Form. This does not require further approval from Sponsor
- A copy of the local disposal/destruction policy should be filed in the PSF (or file note to location)

Emergency Unblinding

- Unblinding is only carried out where necessary for clinical safety:
  - If required, the clinician should contact the local PI or delegate
  - The PI has autonomy to conduct immediate emergency unblinding and is not required to contact a medical monitor or sponsor prior to unblinding
- PI or delegate will perform unblinding
  - Log-in to access 24-hour TRuST unblinding
  - Complete and sign an unblinding form
- PI is responsible for ensuring that anyone delegated to this role has sufficient training & instructions
- Clinician will decide whether participant remains on IMP
- Emergency unblinding training slide set provides details

Emergency Recall

- Emergency recall may be initiated by Sponsor, Evgen or ALMAC
- Clinical Trial Pharmacies, Principal Investigators, Research Team Staff and the Chief Investigator will be alerted by email
  detailing required action:
  - For CTP stock, for example IMP disposal, quarantine or return
  - For participants in possession of the recalled IMP

IMP Management Plan

- Further details are provided in the STAR-COVID19 IMP management plan

IMP Management Plan

Clinical Trial: SFX-01 treatment for **Acute Respiratory Infections** (STAR-Covid19)

IRAS number: 286251

Chief Investigator: Prof James Chalmers

Sponsor: University of Dundee/NHS Tayside

This document describes the process for IMP management at site. The IMP in this trial is SFX-01 300mg /placebo capsules

Abbreviations / terms used

TM	Trial Manager
CTP	Clinical Trial Pharmacy
IMP	Investigational Medicinal Product
ISF	Investigator Site File
PSF	Pharmacy Site File
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TRuST	Tayside Randomisation System