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PHARMACY MANUAL	
Clinical Study Identifier and Abbreviated Title	223054; A Phase I Clinical Study of GSK5764227 in Patients with Advanced Solid Tumors
Development Phase:	I
Title	A Phase I Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of GSK5764227 for Injection in Patients with Advanced Solid Tumors
Version Number	2
Version Date	27-Aug-2024
BASED ON GSK PHARMACY MANUAL TEMPLATE V2.0 	

Document history	
Version and Date	**Rationale for changes**
Version 1	Initial Version
Version 2	**Section: List of Abbreviations** Change: Removed unneeded abbreviations. **Section: GSK5764227 Dose Preparation** Change: Updated Material of Construction table, corrected IP label, added language to clarify that prior to filtration, the prepared dosing solution may

	exhibit a few small particles, added language to note the use of a 0.2µm PES filter is mandatory. **Section: GSK5764227 Dose Administration** Change: Clarified a 0.2 µm in-line filter made of Polyethersulfone (PES) must be used during administration. If the infusion set does not contain a 0.2 µm in-line filter, an add-on filter which may contain an extension line may be used. **Section: Module 3: Randomization And Blinding Systems** Change: Updated RAMOS NG to RAMOS. Updated contact to https://ramos.gsk.com. **Section: Appendix** Change: Includes the following forms - Site-Based Temperature Excursion Report Form, Temperature Monitor

Contents

LIST OF ABBREVIATIONS

Abbreviation	Definition
CRA	Clinical Research Associate
GMP	Good Manufacturing Practice
GSK	GlaxoSmithKline
ICF	Informed Consent Form
I(M)P	Investigational (Medicinal) Product
RTSM	Randomisation and Trial Supply Management
PM	Pharmacy Manual
TE	Temperature Excursion
TMD	Temperature Monitoring Device

GLOSSARY OF TERMS

Term	Definition
Intervention number	A number identifying an intervention to a participant, according to intervention allocation.
Investigational medicinal/vaccine product (IMP)	An IMP is a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical study, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form. Medicinal products with a marketing authorization are IMPs when they are to be used as the test substance, reference substance, or comparator in a clinical study, provided the requirement(s) in the definition is/are met.
Participant number	A unique identification number assigned to each participant who consents to participate in the study.
Participant	Term used throughout the Pharmacy Manual to denote an individual who has been contacted to participate or who participates in the clinical study as a recipient of the study intervention (treatments/products/control). Synonym: subject
Study intervention:	Term used throughout the clinical study to denote a set of investigational product(s) or marketed product(s) or placebo intended to be administered to a participant.
Temperature excursion	Any temperature that is not in range of the label storage temperature conditions for any period of time or any absence of continuous temperature monitoring. In the frame of reporting, the lack/absence of temperature monitoring documentation has to be considered a temperature excursion.

Transfer of product	Any movement of investigational product and/or study intervention within the same site, between different buildings, lasting generally no more than 30 minutes.

INTRODUCTION

This Pharmacy Manual (PM) has been compiled to assist study personnel in conducting study 223054.

The PM does not replace the protocol; it serves as a supplement to the protocol and contains study conduct information in the form of administrative or detailed technical information that is not mandated for the protocol or protocol amendment.

Any procedures that might involve participant care are described in the protocol and associated approved manuals and NOT in this document.

The PM must be reviewed carefully in conjunction with the protocol and any protocol amendments and associated approved manuals.

By signing the protocol investigator agreement, the investigator agrees to comply with the content of the PM, which will be available before study start.

MODULE 1: INVESTIGATIONAL PRODUCT INFORMATION & ANCILLARY SUPPLIES

Investigational Product (IP)

Investigational Products	Sponsor Supplied	Locally Procured
GSK5764227 for Injection, 100 mg/vial	X	

How will the Investigational Product(s) be provided?

GSK5764227 100 mg/vial, Powder for Solution for Infusion, packaged in 20 mL injection vials made of neutral borosilicate glass tubing (Type I glass, FIOLAX®). Study intervention will provide in labelled 20 mL glass vials and placed into a labelled carton. Each vial and carton will be labelled as required per country requirement.

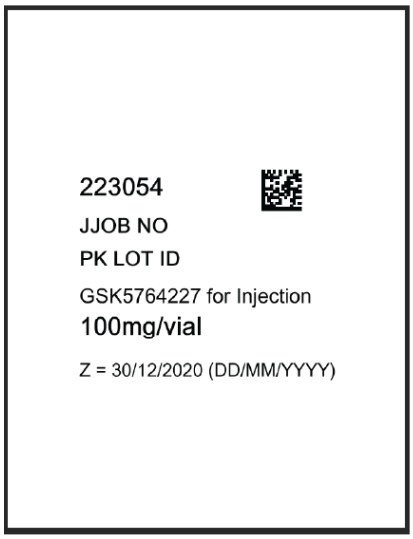
How will the Investigational Product(s) be labelled?

IP will be provided to site with a label that complies with Good Manufacturing Practice (GMP) and regulatory legislation to meet the requirements of the participating country.

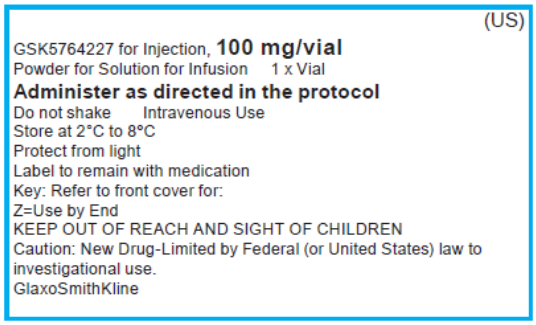
- The IP will be labelled with a booklet label (both vial and carton).
- Booklet labels will have a cover page with lot-specific information (e.g. lot number and expiry date) and pages inside the booklet represent each of the countries with their regulatory requirements. Examples below are for information only, as labels will be country specific and in local language.
- The IP provided will be open-label and non-participant specific.

Carton Label

Example of Cover Page for Carton Booklet Label



Example of page in the Carton Booklet Label



Vial Label

Example of Cover Page for Vial Booklet Label

223054 JJOB NO
PK LOT ID
GSK5764227 for Injection
100mg/vial
Z = 30/12/2020 (DD/MM/YYYY)

Example of page in the Vial Booklet Label

(US)
GSK5764227 for Injection, **100 mg/vial**
Do not shake
Intravenous Use
Key: Refer to front cover for:
Z=Use by End
Caution: New Drug-Limited by Federal
(or United States) law to investigational use.
GlaxoSmithKline

Storage of Investigational Product(s)

- IP is to be stored in a secure area accessible only to authorized individuals.

Product	Storage Temperature	Additional Storage Requirements
GSK5764227 for Injection, 100 mg/vial	Store at 2°C-8°C	Protect from light

For temperature excursion reporting, the allowance range for 2ºC-8ºC (36°- 46°F) is 1.5ºC to 8.4ºC (35°- 47°F). Any temperature excursion outside these allowance ranges for more than 5 minutes is to be reported.

- Written procedures must be available describing the actions to be taken in the event of temperature excursions outside the expected storage temperatures.
- The temperature must be continuously monitored using calibrated Temperature Monitoring Device meeting GSK requirements. At a minimum, the daily minimum and maximum temperature with corresponding date(s) and time(s) of readings must be recorded.
- All temperature data (logs, charts) must be filed in the investigator file. The evidence of maintenance of cold chain must be available for the whole study period when study intervention(s) is administered and up to the final

accountability and reconciliation performed by the CRA. No gaps in temperature monitoring are allowed.

- All temperature excursions outside of the expected storage range for all drug products supplied by GSK must be immediately reported to GSK.
- The Site-Based Temperature Excursion Report Form should be filled out by the site and emailed to GSK at the following email address:

  RD.Clinical-Site-Temperature-Excursions@gsk.com

- Please copy in your Local Delivery Lead and your site monitor/CRA. The drug product(s) must be quarantined at their respective required temperature ranges until further notice.
- The drug product(s) must be quarantined at their respective required temperature ranges until further notice.
- The site monitor/CRA will notify the site, in writing, regarding the disposition of the product (e.g. acceptable for use, return to Sponsor or destroy).

Transportation

- If your site needs to transport IP or prepared drug (refer to Dose Preparation in Module 2), your site must provide either the SOP outlining the transportation process if available, or documentation of site transport policies for GSK to review and approve prior to transportation.

Ordering and Receipt of Initial and Resupply Shipments

IP inventory management	Initial Receipt of IP	IP resupply
RAMOS RTSM refer to RTSM user manual	Site will receive an initial quantity of IP when patient is screened	Automatic via RTSM

Receipt of Investigational Product

All shipments will be accompanied by a temperature monitoring device (WebLogger II). Upon receipt of the shipment, please remove the Temperature Monitor to determine whether a temperature excursion has occurred.

Specific instructions on how to use the Temperature Monitor will be included in the shipment (see Appendix).

Inspect the shipment to ensure that the shipment was received intact, acceptable for use, and that the packing slip matches the contents of the shipment.

For any issues with the shipment please contact GSKClinicalSupportHD@gsk.com immediately.

In-Transit Temperature Excursion Management

If the WebLogger II indicates there was an excursion during transit to the site, the device will automatically send an alert to the mailbox, which can be found on the support page (http://www.clinicalsupporthd.gsk.com/contact.html), once the data from the device has been uploaded. Please also immediately email the GSK CRA/Local Delivery Lead and GSK Supply Chain Study Lead.

Typically, a decision on the usability (or not) of the shipment will be provided within 4 working days.

Where the temperature logger indicates an alarm has been triggered:

1. Immediately place the IP(s) associated with that shipment to "quarantined" status (under labelled storage conditions) to prevent the IP(s) shipment being dispensed to study participants.
2. Upon confirmation that the IP(s) is/are deemed usable following an alarm:
   - Continue with local IP receipt process.
   - File the confirmation in the investigator site file respectively.
3. Upon confirmation that the IP(s) is/are is deemed not usable following an alarm:
   - Make sure the given the
   - IP(s) is/are not available for use
   - Follow local process for IP disposal
   - File the communication in the investigator site file respectively.

Cold-chain IP package and Temperature logger (box and cooling elements left after IP removal and temperature logger upload) is recyclable in some regions and should be returned to GSK central depots as per the instructions included within the shipment using the enclosed return AirWayBill, where included. Please remove IMP and upload the temperature logger before shipping the re-usable packaging and uploaded temperature monitor back to central depot.

Reporting Defects

Any defects in the product should be reported back to GSK for investigation, and the product should be kept at the site for further investigation if required.

MODULE 2: PREPARATION, HANDLING/STORAGE, DOSAGE CALCULATION FOR INVESTIGATIONAL PRODUCT ADMINISTRATION

Handling and Storage of GSK5764227 for Injection 100 mg/vial

- GSK5764227 for injection must be stored at 2-8°C, and be protected from light. The refrigerators in which investigational drugs are stored are intended for use by authorized personnel only and must be calibrated. Storage rooms or refrigerators must have sufficient capacity. GSK5764227 for injection vial should be reconstituted with 5mL sterile water for infusion.
- GSK5764227 reconstituted solutions should be diluted in compendial 0.9% sodium chloride injection or 5% dextrose injection. GSK5764227 dosing solutions should not be diluted or mixed with other diluents.
- GSK5764227 dosing solutions may be stored at room temperature for a cumulative time of up to 4 hours . This includes storage of the solution in the administration container and the duration of the infusion.

If the GSK5764227 dosing solution is not used immediately, it may be stored refrigerated at 2°C to 8°C [36°F to 46°F] for up to 24 hours. If refrigerated, allow the GSK5764227dosing solutions to come to room temperature prior to use.

Do not shake or freeze the prepared dosing solution.

GSK5764227 Dose Calculations

GSK5764227 is dosed based on body weight prior to each dose.

Determine the dose in milligrams required by the subject (weight to be rounded to one decimal point) according to the equation below:

Calculated dose (mg) = subject weight (kg) x patient dosing group {mg/kg}

Patients dosing groups will be between 4mg/kg- 12mg/kg.

Calculate the required volume of GSK5764227 reconstituted dosing solution necessary to prepare the dose using the formula below:

Required drug product volume (mL) = Calculated dose (mg) ÷ 20mg/mL.

GSK5764227 Dose Preparation

GSK5764227 dosing solutions must be prepared aseptically by a pharmacist or appropriate designee. Aseptic technique must be strictly practiced throughout the preparation process. If your site uses gas sterilization as part of your aseptic procedure, the process must be approved by GSK prior to implementation.

After the required volume of GSK5764227 is withdrawn, discard any unused portion remaining in the supplied vial(s), as the product contains no preservative. The vials should only be used for one subject since they are single dose only.

All fluid path materials used in the preparation and administration of GSK5764227 dosing solutions must be constructed from the materials that have been established to be compatible, as listed below. If you are unsure about the materials of construction of your components, the component vendors are available to provide this information. Further support for appropriateness of components for use in this study is available by contacting your site monitor.

Material of Construction
Polyethylene (PE)
Polyethersulfone (PES)
Polyolefin (PO)
Polypropylene (PP)
Polyurethane (PUR)
Polyvinyl Chloride (PVC) (with or without DEHP)

Remove the required number of product vials from 2° to 8°C storage.

Reconstitute the required number of vials by adding 5 mL of sterile water for injection to each vial. Gently swirl the vial until the contents are fully dissolved and the product is uniform in appearance. Do not shake vigorously.

After reconstitution, visually inspect the reconstituted solution prior to preparation. The reconstituted solution is colorless to pale yellow and clear. If visible particles, unusual discoloration or any appearance otherwise not matching the provided description is observed, then the product should not be used. Contact the site monitor to determine if a customer complaint should be raised.

GSK5764227 dosing solutions should be prepared in 0.9% Sodium Chloride Injection, (normal saline) or 5% dextrose injection to a final concentration between 0.4 mg/mL to 12 mg/mL when administered through IV bag.

- Choose a suitable IV bag size to meet the required final concentration requirement of 0.4mg/mL to 12mg/mL
- Empty IV bags may be used for the preparation of GSK5764227 . In this case, use sufficient quantity of diluent to prepare the required concentration.

• Withdraw appropriate volume of GSK5764227 from vial(s) based on patient-specific dose into an appropriately sized syringe, utilizing a new needle for each vial

- If a pre-filled bag is being used, consider removing the reconstituted solution total volume being added to the IV bag prior to dilution (this step is not mandatory as long as concentration remains in range).
- Inject GSK5764227reconstituted solution into the infusion bag.
- Gently invert or massage the infusion bag to mix the dosing solution. Avoid shaking or excessive agitation.

Visually inspect the dosing solution for visible particles, flocculation, or unusual discoloration. Prior to filtration, the prepared dosing solution may exhibit a few small particles, therefore the use of a 0.2µm PES filter is mandatory. The prepared drug is colorless and clear. If unexpected flocculation, unusual discoloration or any appearance otherwise not matching the provided description is observed, then the product should not be used. Contact the CRA to determine if a customer complaint should be raised.

CSTD studies are ongoing and this manual will be updated once results are available. Until then, CSTDs can be used with mandatory use of a 0.2µm PES in-line filter to mitigate the risk of particle formation with CSTD use.

The preferred method of dose preparation is the volumetric method; a gravimetric method is not permitted.

Sites should follow their standard operating procedures for prepared drug transport and delivery, with all possible effort to minimize agitation of the drug product between the pharmacy and the clinic. Do not use a pneumatic tubing system to transport the prepared GSK5764227 dosing solution.

GSK5764227 Dose Administration

Intravenous administration of GSK5764227 dosing solution must be delivered through an IV line with a peripheral line or indwelling catheter using an intravenous infusion pump.

A central catheter is not required for infusion; however, if a subject has a central venous catheter in place, it may be used for the infusion. The catheter must be flushed prior to use to reduce the risk of mixing with other drugs.

A 0.2 µm in-line filter made of Polyethersulfone (PES) must be used during administration. If the infusion set does not contain a 0.2 µm in-line filter, an add-on filter which may contain an extension line may be used.

Prime the infusion line with the GSK5764227 dosing solution or per institutional policy.

Infusion of the GSK5764227 dosing solution should occur over over 90 minutes for the first IV infusion. For subsequent infusions, GSK5764227 should be administered over about 60 minutes if prior infusions were well tolerated.

Administration period	Route of administration	Infusion pump	Infusion set specification	Duration of administration

First dose	IV drip	Yes	0.22 µm	90 minutes
Follow-up visit	IV drip	Yes	0.22 µm	60 minutes

At the end of infusion, flush the infusion line with diluent per institutional practice. Volume of flush should be (at minimum) consistent with the volume of drug that is held in the line. The flush should be administered using the same final rate as the product.

Do not administer other drugs through the same infusion line.

MODULE 3: RANDOMIZATION AND BLINDING SYSTEMS - RTSM

RAMOS (Registration And Medication Ordering System) is an online clinical trials management and monitoring tool that will be utilized for this study.

Please refer to the study-specific User Guide for instructions on how to use RAMOS. Site staff should ensure they can access RAMOS prior to screening a participant.

- ## 3.1 Access

Log-in instructions to the RAMOS system will be provided to qualified site personnel.

To access the RAMOS system as an end user for the 223054 study, connect to the RAMOS application via https://ramos.gsk.com. You may need to copy and paste the address into your browser if the link does not work.

Microsoft Edge is recommended as your browser for access to RAMOS (Chrome and Firefox can also be used).

Please notify your monitor/CRA with any personnel changes in order to provision access to RAMOS.

- ## 3.2. Investigator site staff eLearning

All qualified site personnel must complete the RAMOS e-module training before using the RAMOS web-based system. Please contact your study monitor if you require further details.

- ## 3.3. RAMOS Study Specific Guide

A RAMOS Study-Specific Guide will be provided prior to study start.

• 3.4. GSK Support Help Desk

Any issues encountered with RAMOS should be reported to the GSK Clinical Support Help Desk (i.e., log-in issues, medication issue, etc.). The GSK Clinical Support Help Desk (CSHD) is available 24/7 including holiday periods.

The CSHD can be contacted via telephone or email (GSKClinicalSupportHD@gsk.com). For a listing of country specific toll free & direct numbers visit http://www.clinicalsupporthd.gsk.com/contact.html.

Please make sure that you provide a telephone number where you can be reached right away. Inquiries received by the GSK Clinical Support Help Desk will be categorized as listed below. If you call the helpdesk about a problem with randomizing the participant, tell the helpdesk that this is a "critical" or "urgent" situation, depending on the circumstances.

- **CRITICAL** – Requires immediate attention such as:
  - RAMOS is unavailable. It will be up to the RAMOS helpdesk to determine if it is worldwide or country specific.

- **URGENT** – Concern for participant's welfare or convenience, or there is a time-critical situation such as:
  - Log on issues to RAMOS while a participant is on site.

- **HIGH PRIORITY** - Critical situation where a participant is expected to be randomized on the following day or when calls are from monitors and study management such as:
  - Site/Study overall limits changes, system access, role access.

- **MEDIUM/LOW** - Non-time critical information or actions such as:
  - Changing status of study or site (Place study or site status on hold).

APPENDIX 1

COMPLETED FORM IS NOT TO BE UPLOADED TO VEEVA

Send to RD.Clinical-Site-Temperature-Excursions@gsk.com Ref No:

Site-Based, Depot & In-Transit from Local Depot Temperature Excursion Form

PART A					
Sections 1-3 to be filled out by Site, then e-mailed to GSK (email addresses in header)					
Section 1: Details of Study, Site/Centre, Country, Temperature Excursion:					
Study#:		**Site/Centre or alternative location:**		**Country:**	
Person Reporting Excursion:		**Email:**			
Discovery	**Date:**				
Start of Excursion:	**Date:**				
End of Excursion:	**Date:**				
Total Duration:	**Hours/Minutes:**				
Highest Temp:	**0°C**				
Lowest Temp:	**0°C**				

Section 2: Details of affected Treatment Supplies					
Product:		**Strength:**		**Job No/ Orderable Lot No**	

				Shipment #	
Container # ranges: (if applicable)					
Unique Batch/Lot No **(Tesaro studies only)**					
Product:		**Strength:**		**Job No/ Orderable Lot No**	
				Shipment #	
Container # ranges: (if applicable)					
Unique Batch/Lot No **(Tesaro studies only)**					

Section 3: Reason for Excursion	
Reason for Excursion (tick relevant box)	

Environmental factor (climate related issues)	
Unknown/Other (unknown cause of temperature excursions)	
Process (Temperature excursion caused due to issue with process)	
In Transit (Temperature excursion that occurred during transit)	
Temperature Monitoring Device issue (TMD device did not record)	
Equipment issue (Issue with fridge or freezer (i.e battery failed))	
Human Error (Issues caused by people that were preventable)	

Sections 4 - 12 to be completed by Supply Chain Assistant Team		
Section 4: Excursion decision		
Is this deemed to be an excursion? **(delete as appropriate)**	**Yes/No**	**If Yes, go to PART B** **If No, complete Section 4 & 5 then sign section 6. Section B can be scored through / deleted as appropriate**
Storage condition from LDC (or equivalent) **(only complete if non-excursion):**		
Reason for non-excursion (if applicable)	**As per the acceptable duration in Table 1 of tech memo 2018N374438 listed in VQD-SOP-004924, supplies are suitable for use.**	
Section 5: Comments		
Section 6: SCA Author signing to confirm that the information contained on the form is true and accurate and the assessment has been completed as per VQD_SOP_004924 . SCA Author Name, Signature & Date.		

Section 7: Approval by SCA Team Leader, Subject Matter Expert (SME) or QA to confirm that as approver they accept that the results of the assessment are correct and have been completed as per VQD_SOP_004924. Name, Signature & Date.

PART B: To be completed in the event of an excursion

Section 8: Previous Excursions (to be used for cumulative assessment only)		
Is this a cumulative Product	**Yes / No**	**If no, the remaining boxes in Section 8 can be scored through / deleted**

Is this a repeat occurrence at this site? **(delete as appropriate)**	**Yes/No**	**Same Job Number/Orderable Lot No** **Same Container?**	
Frozen Product **(delete as appropriate)**	**Yes/No**	**Freeze Thaw Occurrences?** **(Always required with Frozen products)**	
Audit & Quality Management System check completed against Job No/ Orderable Lot No reported	**Yes/No**		
In-transit check completed against job No/Orderable Lot No reported & Packaging to Distribution sites	**Yes/No**		
Cumulative time out of limits:	**High:**		

(as per section 7.2.4 & 7.2.5 of VQD-SOP-004924) **<u>Cumulative high and low to be shown separately</u>**	**Low:**
Ref No's of previous excursions: **(Cumulative or freeze thaw excursions only)**	

Section 9: IMP Details

Section 9.1: Impact Assessment for Treatment Supplies	
Storage condition from LDC (or equivalent):	
Stability data reference & Version No	
Are the affected supplies suitable for use? (delete as appropriate)	**Yes/No**

Section 10: Comments
Section 11: SCA Author signing to confirm that the information contained on the form is true and accurate and the assessment has been completed as per VQD_SOP_004924. **SCA Author Name, Signature & Date**

Section 12 to be completed by GSK QA Operations/SCA Team Leader / Subject Matter Expert (SME)
Section 12.1: Approval by SCA Team Leader / Subject Matter Expert (SME) to confirm that as approver they accept that the results of the assessment are correct and have been completed as per VQD_SOP_004924. Approver Name, Signature & Date. ****FOR USE WITH NO STABILITY INFORMATION AVAILABLE OR EXCURSIONS AT PATIENTS HOME ONLY****
Section 12.2: Approval by GSK QA Operations to confirm that as approver they accept that the results of the assessment are correct and have been completed as per VQD_SOP_004924 (Formerly SOP_354818). **Approver Name, Signature & Date.**

APPENDIX 2

**IMPORTANT RECEIVING AND HANDLING INSTRUCTIONS FOR THIS CLINICAL TRIAL MATERIAL SHIPMENT
FROM GLAXOSMITHKLINE**

RETAIN THIS FORM WITH YOUR STUDY DOCUMENTS

A Temperature Recording device is included inside this shipping container.

Please follow the instructions IMMEDIATELY upon receipt.

If there are any problems when uploading the Temperature Monitor, please call CSHD.

http://www.clinicalsupporthd.gsk.com/contact.html

DO NOT DISPENSE TO PATIENTS OR CONFIRM IN IRT (RAMOS, CENDUIT, SUVODA, etc) UNTIL MED HAS BEEN APPROVED FOR USE.

If a shipment was received under quarantine in the IRT and is subsequently confirmed acceptable for use, the appropriate IRT helpdesk must be contacted to update the shipment status.

2. STEP BY STEP INSTRUCTIONS FOR RECEIVING SHIPMENTS

No software is installed on the computer when uploading the Monitor

1. **Press and Hold the red Stop button on the device until the "RED Stop light" appears in the upper LED display**

NOTE: If the stop button isn't pressed immediately upon removal for 3-5 seconds, an alarm is likely. This will require progressing via the site based alarm process.

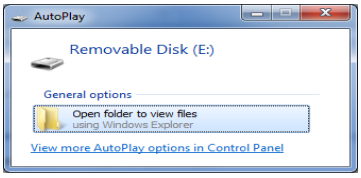
2. **Note the date and time the data logger was stopped upon unpacking shipment**

   Order Ref: _____ Date and Time: _____ (this information will be required in step 7)

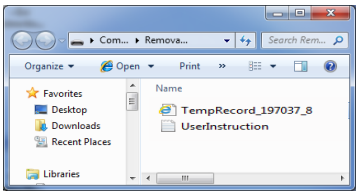
   Plug-in the device to a USB port on your computer - A folder will be displayed (similar to the process to plugging in a camera or USB stick)

3. 

   - **If the folder is not displayed, it is found as a removable disk on the computer**



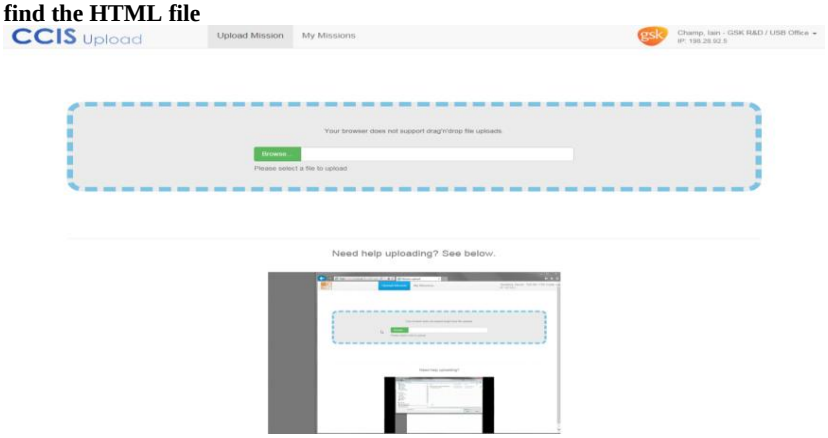
4. **In the folder, double click on the html file (TempRecord_XXXXXX_X.htm or Click_Here_To_Upload.html)**



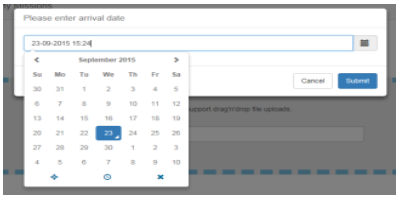
5. **The default browser will open the registration page**
   - **If you are a registered user: select "Already registered" and log in**
   - **You may have to approve and allow the application to execute**

Please turn over for more instructions

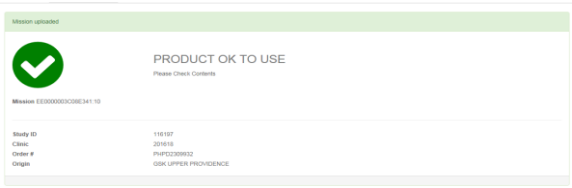
6. **Once logged in, there are two ways of uploading either drag and dropping the HTML file or click on browse to find the HTML file**



7. **Enter Arrival Date and Time upon login as instructed in step 1 above**

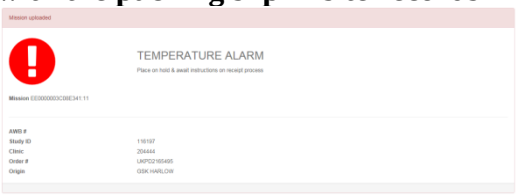


8. **A popup box will appear on the screen showing "Product Usable". Proceed per local GSK receipt process.**
   Please use the PDF button to Save or Print the confirmation of the upload and store with the packing slip in site records



9. **If an excursion has occurred, the screen will show "Temperature Alarm" and will ask for the supplies to be placed "On hold". An automatic email will be sent to the site of origin immediately who will start the excursion management process and then reply back to your email to let you know if the product is okay to use or not.**

Please use the PDF button to Save or Print the confirmation of the upload and store with the packing slip in site records



Troubleshooting

1. **If a warning message appears e.g. "You are about to open an external link": Click "allow to continue" (wording may differ depending on the system)**
2. **If the drag and drop of the "Click_Here_To_Upload" or "TempRecord_xxxxxx_xx" file is not supported by your browser you can select "browse" and select the file "Click_Here_To_Upload" or "TempRecord_xxxxxx_xx" from the folder "TSS_WLR2"**Components

Components

Temperature Monitor

Return for Recycle

Once the Weblogger temperature monitor has been uploaded to CCIS Website - Return the Temperature Monitor with the shipper to be recycled or Dispose of Monitor locally.

APPENDIX 3

Clinical Trials Customer Complaint Notification Form (v2)

Complaint Reporter Details			
Name, Role & Address of Complaint Reporter	Do not include any Patient Personally Identifiable Information (PII)	Country	
Local / Primary Contact Name, Role, Phone Number & Email			
Study Name/Number			
Site Name			
Site Number			
Incident occurrence date (DD/MMM/YYYY):			
Incident detection date (DD/MMM/YYYY):			

Complaint Material Details	
Type of defective unit(s)	☐ Box ☐ Vial ☐ Bottle ☐ Label ☐ Syringe (Vaccine only) Other: .....
Product Name / Strength	
Batch/Material Details	Batch / Job No:_____ _____

	Kit/treatment No:_____ Patient No:_____ Expiry date:_____
Was the impacted material administered?	☐ Yes ☐ No ☐ Partial dose If required, was the replacement dose administered? ☐ Yes ☐ No N/A ☐
Shipment Number (If applicable)	
Study blinding	☐ Yes / ☐ No If yes, ☐ Single Blinded ☐ Double Blinded
Complaint sample status	☐ Available for return ☐ Not available for return **NOTE**: Retain all defective samples and return upon instruction from GSK.
Picture available	☐ Yes ☐ No If yes, please send the picture (showing product defect and lot number labeling) attached to this template.

Complaint Description
List details of the complaint including, • Problem • When/how it occurred • Number of defective units involved
Corrective actions taken by the site (if applicable)
Is this complaint a result of an Adverse Event or Serious Adverse Event? ☐ Yes / ☐ No (If yes describe what occurred, patient outcome e.g. resolved, withdrawal from the study)
Is this a result of a Non-Compliance Patient /Clinical Site Error /Study protocol manual not followed? ☐ Yes / ☐ No (if yes describe what occurred)

Return the completed form and any supporting photographs to the applicable mailbox below:

- be.ct-qa-systems@gsk.com(Vaccines studies)
- gsk-rd.complaints@gsk.com (Pharma R&D studies)