rFVIIa for Acute Hemorrhagic Stroke Administered at Earliest Time (FASTEST) Trial

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Prior to Readiness call/SIV

Complete site Pharmacy regulatory

Receive study drugs

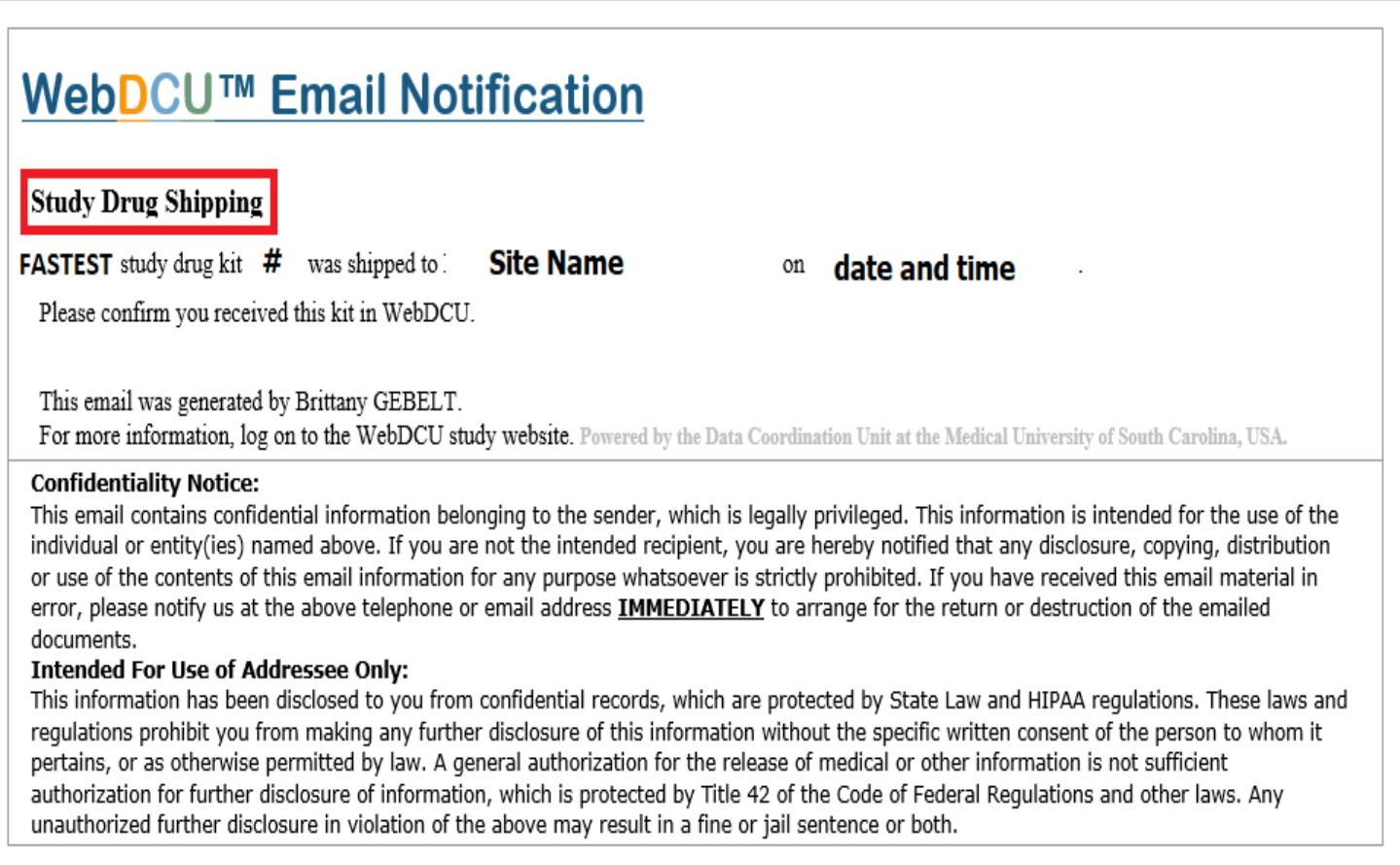
Readiness call/SIV

(Ask questions!)

Site Pharmacy Regulatory in WebDCU™

- Drug Destruction Policy/SOP or explaining note to file must be provided by site to CRO and uploaded into WebDCU™ by CRO
- Note to file stating/providing justification that no site pharmacy will be used must be uploaded into WebDCU™ by CRO
- Drug shipping address must be provided by site to CRO and entered into WebDCU™ by CRO
- The DOA includes at least one qualified person with pharmacy privileges
- When a Clinical Performing Site (CPS) is released to receive study drug, an initial study drug shipment will automatically be submitted to European Central Pharmacy by WebDCU™
- European Central Pharmacy ships study drug kits few days prior to readiness call/SIV to be received by site 1-2 days prior to call/SIV
- European Central Pharmacy will ship study drug kits Monday through Thursday for next day delivery. No shipments will take place for receipt on Saturday, Sunday, or holidays, except under extenuating circumstances

WebDCU™ Study Drug Shipping Email



WebDCU™ Email Notification

Study Drug Shipping

FASTEST study drug kit **#** was shipped to: **Site Name** on **date and time** .

Please confirm you received this kit in WebDCU.

This email was generated by Brittany GEBELT.
For more information, log on to the WebDCU study website. Powered by the Data Coordination Unit at the Medical University of South Carolina, USA.

Confidentiality Notice:
This email contains confidential information belonging to the sender, which is legally privileged. This information is intended for the use of the individual or entity(ies) named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or use of the contents of this email information for any purpose whatsoever is strictly prohibited. If you have received this email material in error, please notify us at the above telephone or email address **IMMEDIATELY** to arrange for the return or destruction of the emailed documents.

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- CPSs will receive an automated email from WebDCU™ for every study drug kit that was processed out of WebDCU™ for shipment.
- For example, if a shipment has 4 study drug kits in the shipment, the CPS will receive an individual email for each kit (4 emails).
- If arrival of shipment appears delayed, CPS should contact the EU Central Pharmacy via Email: v-apoth.studien@med.uni-heidelberg.de
  EU Central Pharmacy can track shipment via MARKEN Waybill number and will forward status to CPS.

FASTEST

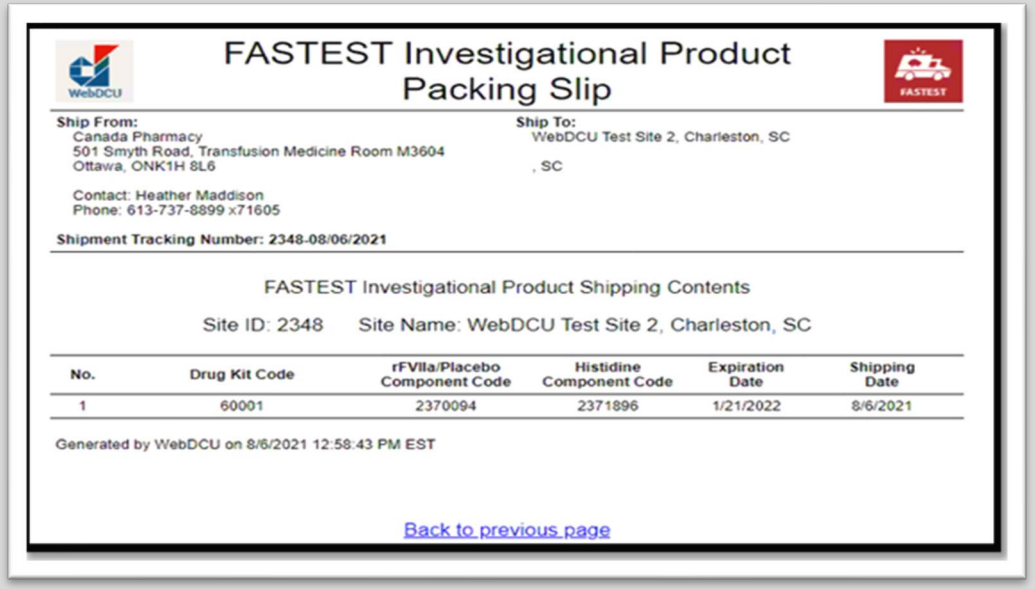
Study Drug Packaging and Packing Slip

Study drugs will be shipped refrigerated

Study drug will be shipped with a USB temperature logger, cold packs, and enough insulation to maintain a temperature range of 2°-25°C for at least 96 hours
(Cold packs and outer box will be collected and taken back by courier MARKEN upon delivery)

Insulated Shipping Container

Temp-Tale



FASTEST Investigational Product Packing Slip

Ship From:
Canada Pharmacy
501 Smyth Road, Transfusion Medicine Room M3604
Ottawa, ONK1H 8L6

Contact: Heather Maddison
Phone: 613-737-8899 x71605

Ship To:
WebDCU Test Site 2, Charleston, SC
, SC

Shipment Tracking Number: 2348-08/06/2021

FASTEST Investigational Product Shipping Contents

Site ID: 2348 Site Name: WebDCU Test Site 2, Charleston, SC

No.	Drug Kit Code	rFVIIa/Placebo Component Code	Histidine Component Code	Expiration Date	Shipping Date
1	60001	2370094	2371896	1/21/2022	8/6/2021

Generated by WebDCU on 8/6/2021 12:58:43 PM EST

Back to previous page

Packing Slip

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PREVENTION | TREATMENT | RECOVERY

FASTEST

Example Kit Label

Study Drug Kit ID

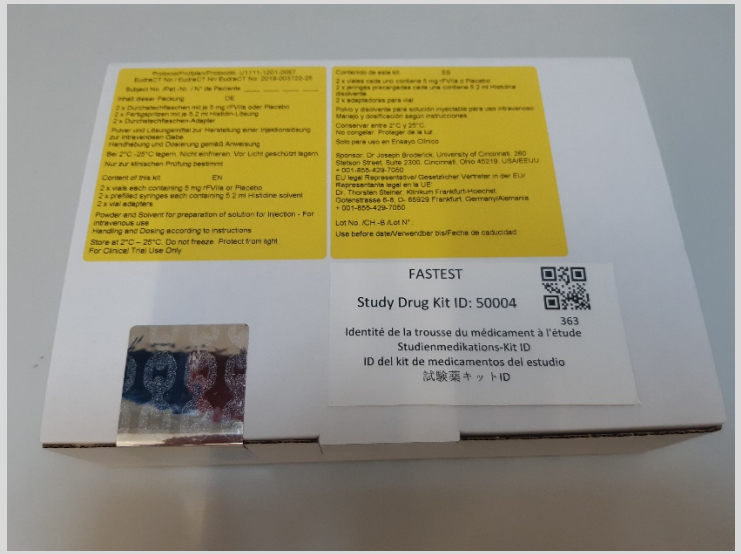
FASTEST
Study Drug Kit ID: 32565
621

Identité de la trousse du médicament à l'étude
Studienmedikations-Kit ID
ID del kit de medicamentos del estudio
試験薬キットID

Verification code

Study Drug Kit Box

Size: 22,5 cm x 16 cm x 5 cm



Protocol/Prüfplan/Protocolo: U1111-1201-0087 EudraCT No / EudraCT Nr/ EudraCT No: 2019-003722-25		
Subject No. /Pat.-Nr. / N° de Paciente ____ ____ ____ ____		
Inhalt dieser Packung: DE	Content of this kit: EN	Contenido de este kit: ES
2 x Durchstechflaschen mit je 5 mg rFVIIa oder Placebo 2 x Fertigspritzen mit je 5,2 ml Histidin-Lösung 2 x Durchstechflaschen-Adapter	2 x vials each containing 5 mg rFVIIa or Placebo 2 x prefilled syringes each containing 5.2 ml Histidine solvent 2 x vial adapters	2 x viales cada uno contiene 5 mg rFVIIa o Placebo 2 x jeringas precargadas cada una contiene 5.2 ml Histidina disolvente 2 x adaptadores para vial
Pulver und Lösungsmittel zur Herstellung einer Injektionslösung zur intravenösen Gabe Handhabung und Dosierung gemäß Anweisung	Powder and Solvent for preparation of solution for injection - For intravenous use Handling and Dosing according to instructions	Polvo y disolvente para solución inyectable para uso intravenoso Manejo y dosificación según instrucciones
Bei 2°C -25°C lagern. Nicht einfrieren. Vor Licht geschützt lagern.	Store at 2°C – 25°C. Do not freeze. Protect from light.	Conservar entre 2°C y 25°C. No congelar. Proteger de la luz.
Nur zur klinischen Prüfung bestimmt	For Clinical Trial Use Only	Solo para uso en Ensayo Clínico.
Sponsor: Dr Joseph Broderick, University of Cincinnati, 260 Stetson Street, Suite 2300, Cincinnati, Ohio 45219, USA/EEUU + 001-855-429-7050 EU legal Representative/ Gesetzlicher Vertreter in der EU/ Representante legal en la UE: Dr. Thorsten Steiner, Klinikum Frankfurt-Hoechst, Gotenstrasse 6-8, D- 65929 Frankfurt, Germany/Alemania + 001-855-429-7050		
Lot No. /CH.-B./Lot N°.:	Use before date/Verwendbar bis/Fecha de caducidad:	

European kit label

- Country-specific **blinded kit labels**
- Kits are tampered evident sealed. **It is required not** to break the tamper evident seal until the kit is dispensed
- Two lot numbers will be printed on the kit label (rFVIIa/placebo as well as histidine lot no.)

Study Drug Receipt

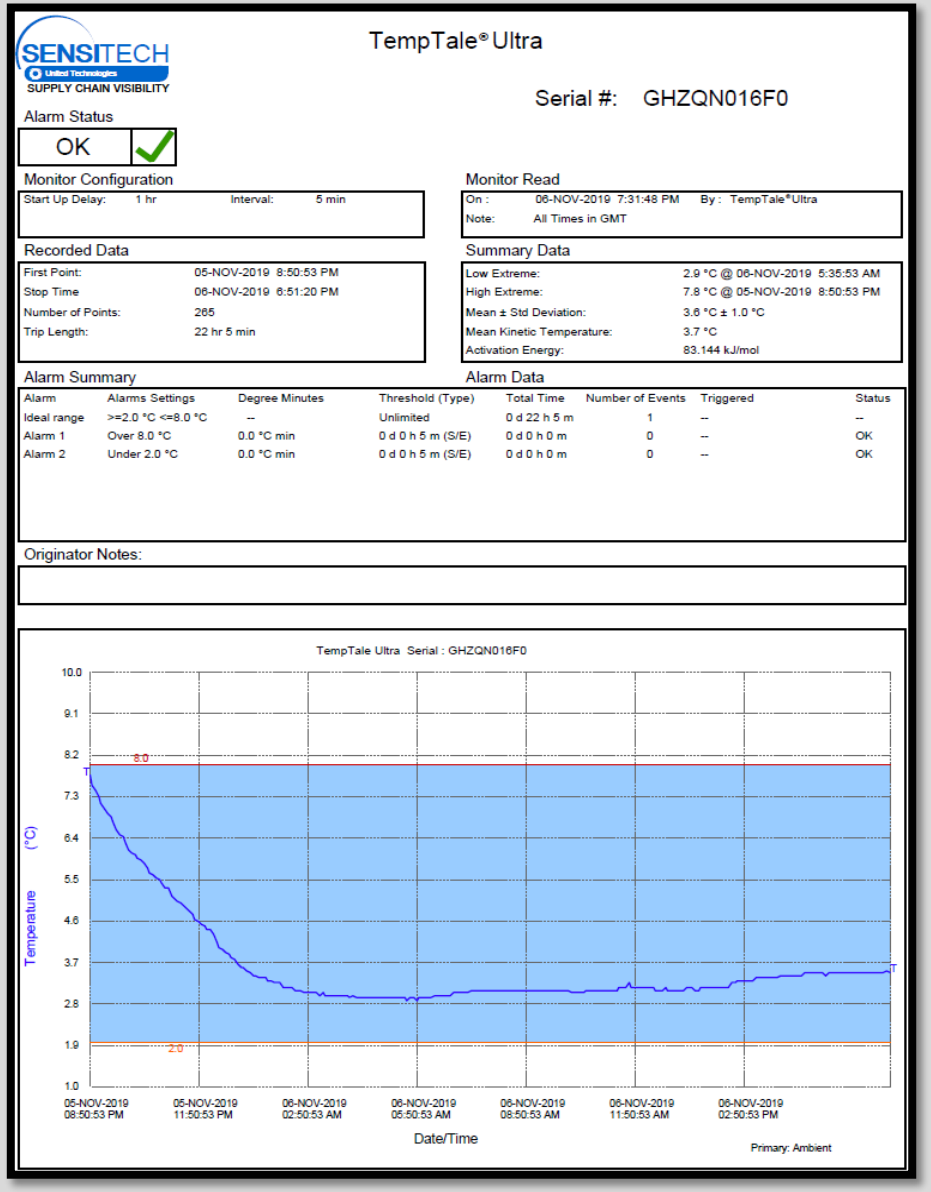
- The initial study drug shipment will contain a total of two study drug kits to sites with one enrolling location (ED or MSU) and four study drug kits to sites that have two enrolling locations (ED+MSU) or 2 EDs

- Upon receipt of the drug shipment, the CPS will verify the receipt of the study drug kit(s) against the packing slip

- The CPS will review the temperature data from the USB logger and confirm that the study drug did not experience any temperature excursions in transit (next slide)
  - CPS should let European Central Pharmacy know beforehand if logger read out cannot be done onsite. In this case, the courier will have to take the logger back and do the read out.

- Study drug kits cannot be dispensed until received into WebDCU™ **and** site is released to enroll

Example Data Logger Report



SENSITECH
United Technologies
SUPPLY CHAIN VISIBILITY

TempTale® Ultra

Serial #: GHZQN016F0

Alarm Status

OK

Monitor Configuration

Start Up Delay:	1 hr	Interval:	5 min

Monitor Read

On :	06-NOV-2019 7:31:48 PM	By :	TempTale®Ultra
Note:	All Times in GMT		

Recorded Data

First Point:	05-NOV-2019 8:50:53 PM
Stop Time	06-NOV-2019 6:51:20 PM
Number of Points:	265
Trip Length:	22 hr 5 min

Summary Data

Low Extreme:	2.9 °C @ 06-NOV-2019 5:35:53 AM
High Extreme:	7.8 °C @ 05-NOV-2019 8:50:53 PM
Mean ± Std Deviation:	3.6 °C ± 1.0 °C
Mean Kinetic Temperature:	3.7 °C
Activation Energy:	83.144 kJ/mol

Alarm Summary

Alarm Data

Alarm	Alarms Settings	Degree Minutes	Threshold (Type)	Total Time	Number of Events	Triggered	Status
Ideal range	>=2.0 °C <=8.0 °C	--	Unlimited	0 d 22 h 5 m	1	--	--
Alarm 1	Over 8.0 °C	0.0 °C min	0 d 0 h 5 m (S/E)	0 d 0 h 0 m	0	--	OK
Alarm 2	Under 2.0 °C	0.0 °C min	0 d 0 h 5 m (S/E)	0 d 0 h 0 m	0	--	OK

Originator Notes:

TempTale Ultra Serial : GHZQN016F0

Temperature (°C)

10.0 9.1 8.2 7.3 6.4 5.5 4.6 3.7 2.8 1.9 1.0

8.0

2.0

05-NOV-2019 08:50:53 PM
05-NOV-2019 11:50:53 PM
06-NOV-2019 02:50:53 AM
06-NOV-2019 05:50:53 AM
06-NOV-2019 08:50:53 AM
06-NOV-2019 11:50:53 AM
06-NOV-2019 02:50:53 PM

Date/Time

Primary: Ambient

1. Once the data logger arrives at the CPS ➡ stop the data logger by pressing the red STOP button for 1-3 seconds until the stop sign logo appears in the top right corner of the LCD display.

2. Insert the data logger into a USB port of a computer at the CPS.

3. View the PDF temperature data log and review the data log for temperature excursions.

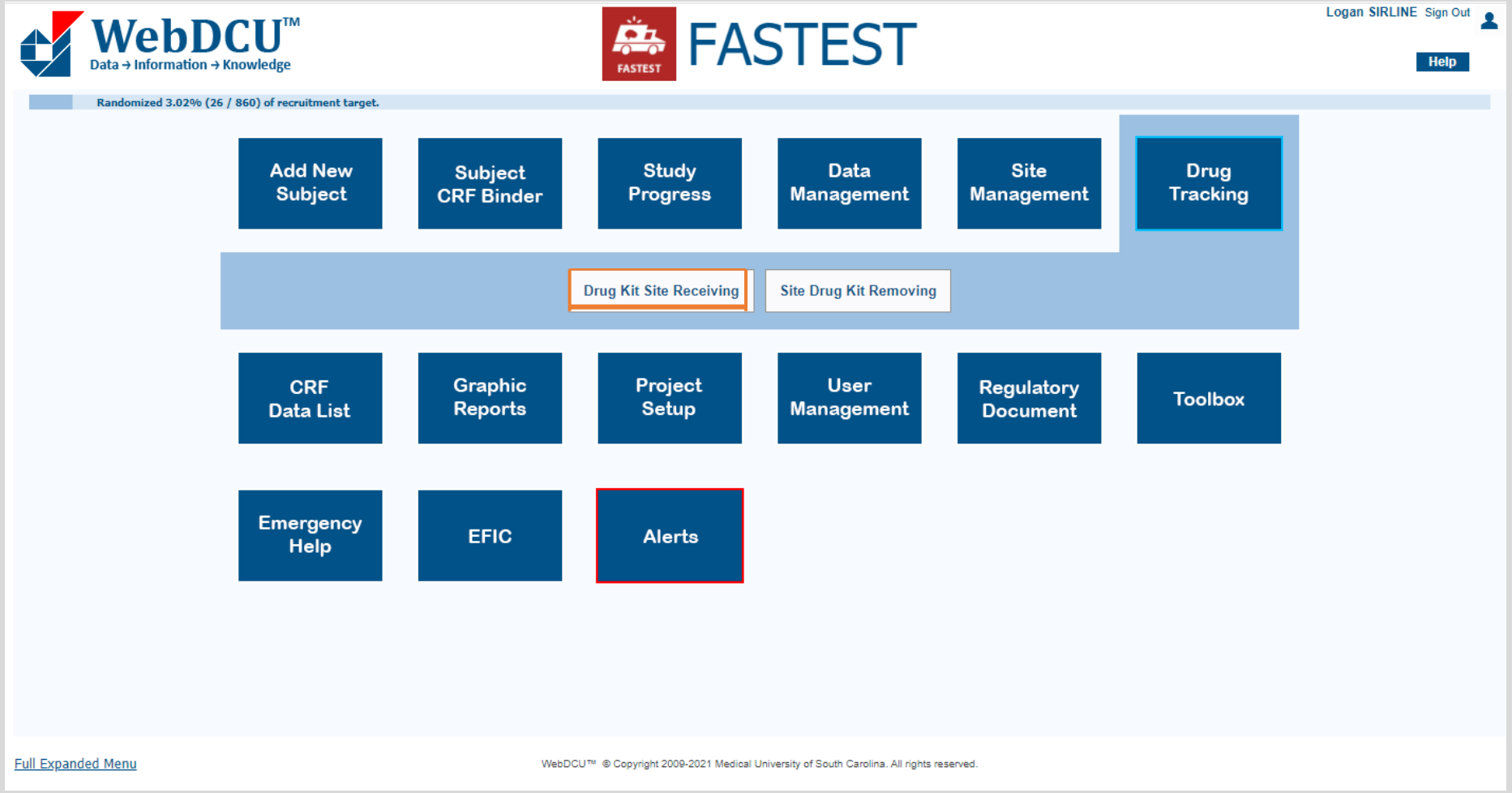
4. Print and file the temperature data log in the FASTEST trial binder to be available during monitoring visits.

5. Once the data has been retrieved from the logger and the temperature curve is printed, the temperature logger can be disposed of per the institution's policy.

6. If **NO** temperature excursions or discrepancies are identified, the CPS will confirm receipt of all study drug kits in WebDCU™ Drug Tracking>Drug Receiving.

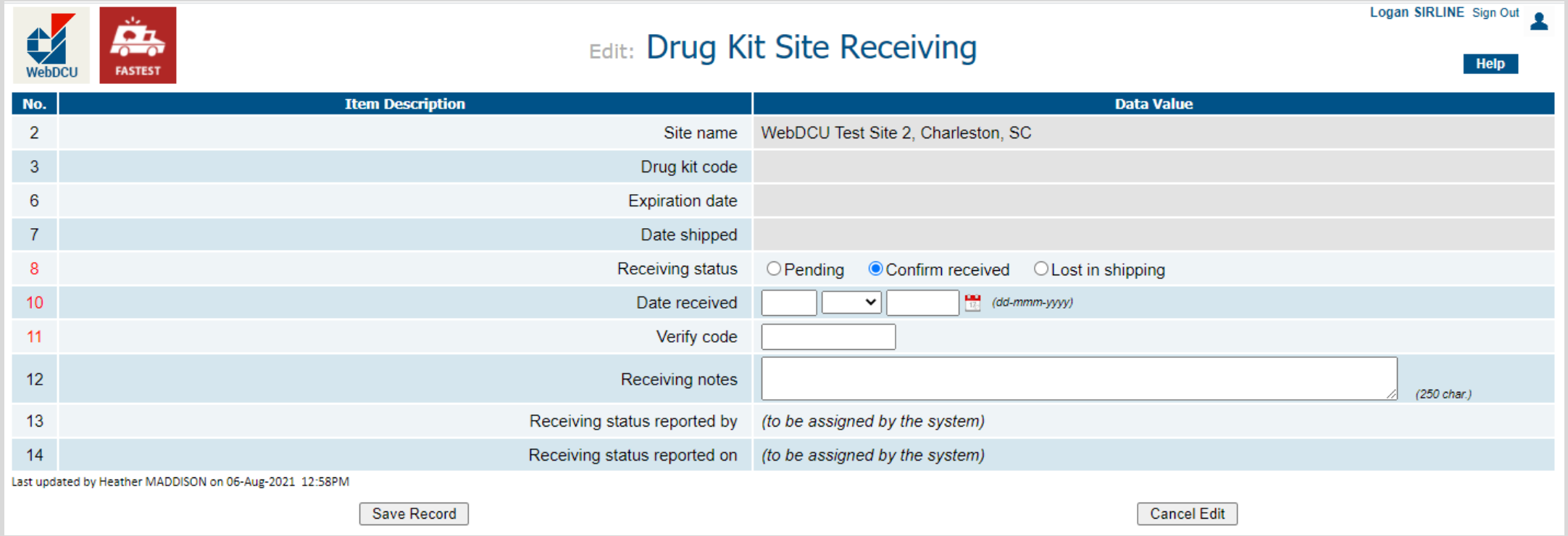
FASTEST

Drug Tracking



FASTEST

Receiving Drug



WebDCU FASTEST

Logan SIRLINE Sign Out

Edit: Drug Kit Site Receiving

Help

No.	Item Description	Data Value
2	Site name	WebDCU Test Site 2, Charleston, SC
3	Drug kit code	
6	Expiration date	
7	Date shipped	
8	Receiving status	○ Pending ◉ Confirm received ○ Lost in shipping
10	Date received	(dd-mmm-yyyy)
11	Verify code	
12	Receiving notes	(250 char.)
13	Receiving status reported by	*(to be assigned by the system)*
14	Receiving status reported on	*(to be assigned by the system)*

Last updated by Heather MADDISON on 06-Aug-2021 12:58PM

Save Record Cancel Edit

- If study drug kit(s) are not received into WebDCU™ **within 3 days** of shipment, the CPS will receive an automated email notification prompting them to receive the study drug kit(s) in WebDCU™

FASTEST

Study Medication Storage/Shipping Conditions

Novo Nordisk

- Novo will be shipping to the Central Pharmacy Depots at 2-8°C.

European Central Pharmacy

- **Storage and shipping:** Study medication stored and will be shipped refrigerated.

Clinical Performing Sites

- Storage: Study medication can be stored (without preference) at room temperature or refrigerated, however, temperature MUST be continuously monitored.
- The permitted range for Germany: 2-25°C
- Sample temperature monitoring logs will be provided and available in WebDCU™
  - Toolbox>Project Documents

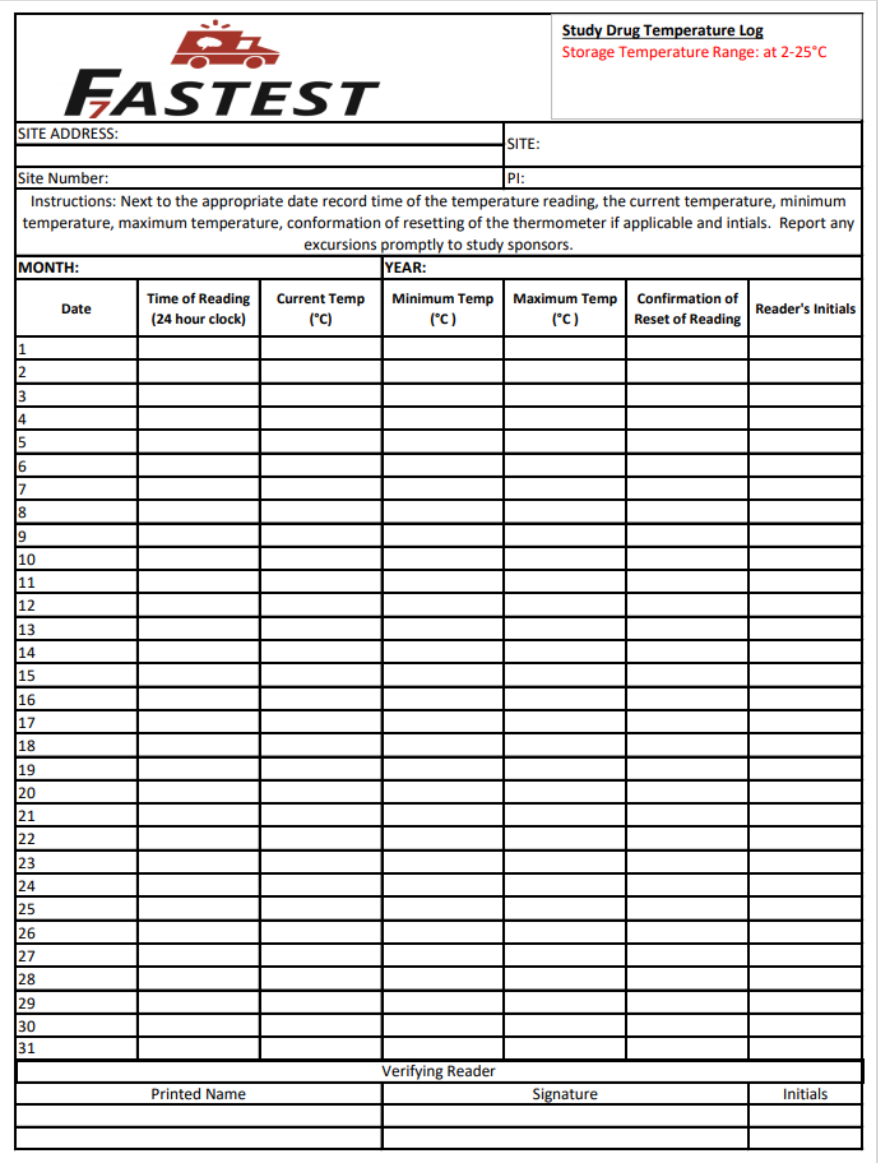
FASTEST

Temperature Monitoring Log Example

CPSs are required to **maintain continuous temperature monitoring** logs at <u>each</u> enrolling location

Sample temperature monitoring logs will be provided and available in WebDCU™

Toolbox>Project Documents



FASTEST

Study Drug Temperature Log

Storage Temperature Range: at 2-25°C

SITE ADDRESS:	SITE:
Site Number:	PI:

Instructions: Next to the appropriate date record time of the temperature reading, the current temperature, minimum temperature, maximum temperature, conformation of resetting of the thermometer if applicable and intials. Report any excursions promptly to study sponsors.

MONTH:			YEAR:			
Date	Time of Reading (24 hour clock)	Current Temp (°C)	Minimum Temp (°C)	Maximum Temp (°C)	Confirmation of Reset of Reading	Reader's Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Verifying Reader		
Printed Name	Signature	Initials

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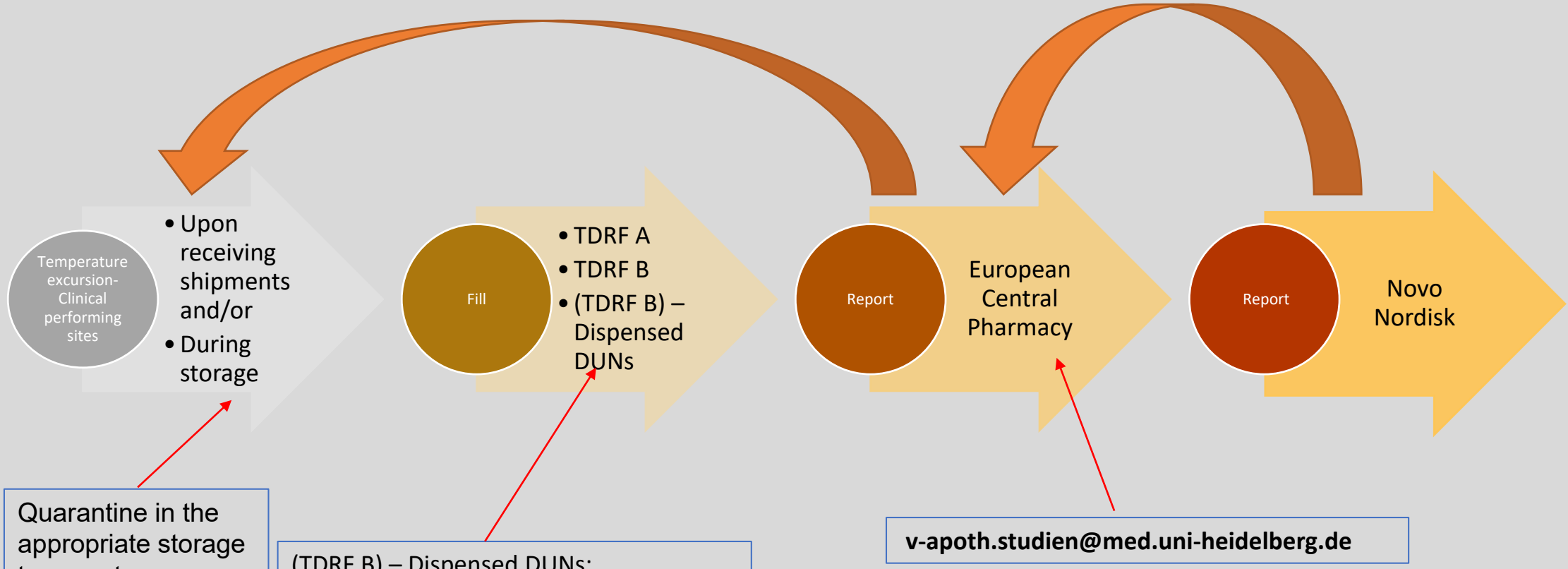
Temperature Excursions

A temperature excursion occurs when **in-transit or onsite drug storage** temperatures fall outside of acceptable temperature ranges.

- A temperature excursion should be reported if storage temperature falls below 2°C and/or rises above 25°C.
- US Pharmacopeia (USP) rounding rules do apply for the temperature excursion (i.e., 1.5°C is rounded up to 2°C and 25.4°C is rounded down to 25°C. Both examples are **not** a reportable excursion.).
- Any temperature excursion affecting FASTEST study drug kits must be reported immediately, preferably within **48 hours** of occurrence.

In-Transit Temperature Excursion: If study drug experiences a temperature excursion in-transit, do NOT receive kits into WebDCU™ inventory. Study drug kits are available for randomization once they are marked as received in WebDCU™.

Reporting Temperature Excursions to Novo Nordisk A/S at **Site**



Temperature Deviations

Temperature Deviation Report Form A – Site

Instructions:

- Please complete the form in its entirely. Fields marked with * are mandatory.
- Green text is guidance text and should be deleted before use.
- Email this form and all relevant temperature logs to European Central Pharmacy, at v-apoth.studien@med.uni-heidelberg.de
- US Pharmacopeia (USP) rounding rules apply for temperature excursions. i.e., 1.5°C is rounded up to 2°C and 25.4°C is rounded down to 25°C. Both examples are not a reportable excursion.

General information

*Trial ID: U1111-1201-0087/ FASTEST	*Site number:
*Country:	*Prioritisation date eg, next dispensing date or DBL date: Not known or N/A ☐
*Has the product affected by the deviation been dispensed to subjects?	Yes ☐ No ☐ If **no**, please complete Temperature Deviation Report Form B (**Page 2 of this document**) If **yes**, please complete Temperature Deviation Report Form B, Dispensed DUNs. (**Page 3 of this document**)
*Type of deviation Storage deviation: ☐ Attach graph/ logs Shipment deviation: ☐ Attach graph/ logs	Logger ID: Logging interval for storage temperature monitoring device Logger ID:

Description of the deviation

*Date/period of deviation Include time if relevant Start date/time: Stop date/time:	*Temperature Too warm: ☐ Too cold: ☐ compared to allowed temperature range Highest/lowest temperature:

Additional information: Only if relevant to the case evaluation, for example arrival time of the products if the temperature deviation is due to data logger not stopped upon arrival

Example: Above 30° for 45 min
Below 2° for 120 min

*It is confirmed that the products are stored, quarantined and within allowed temperature range.

Initials: Date:

- Fill in TDRF-A

Temperature Deviation Report Form B – Site

Green text is guidance text and should be deleted before use.

Please complete the form electronically and submit with the TDRF A. Fields marked with * *must* be completed.

Trial and site information

*Trial ID: U1201-0087/ FASTEST	*Site number: For example, "102"

Trial product information

*IWRS used	Yes ☐ No ☒
*If IWRS is used: Affected product status has been changed to "temporarily unavailable" in the IWRS.	Yes ☐ N/A ☒

Specific for deviations during shipment

* Shipment tracking no:	

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded Lot no (if applicable)	*Kit (list all Kits for the specific lot)	*DUN/component code no (list all DUN for the specific batch)

Specific for deviations during storage

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded lot no (if applicable)	*Shipment no	*Kit (list all kits for the specific lot)	*DUN/ component code no (list all DUN for the specific batch)

- Fill in TDRF-B

- Fill in TDRF-B, Dispensed DUNs

Temperature Deviation Report Form B, Dispensed DUNs – Site

Green text is guidance text and should be deleted before use.

Please complete the form electronically and submit with the TDRF A. Fields marked with * *must* be completed.

Trial and site information

*Trial ID: U1201-0087/ FASTEST	*Site number: For example "102"

*Please list all trial products involved in the deviation

*Product name	*Lot no/coded lot no (if applicable)	*Shipment no	*kit (list all Kits for the specific lot)	*DUN (list all DUNs for the specific kit)	*Date dispensed

Trial ID: U1201-0087/FASTEST
Site number: Unique description
Country:
Prioritisation date: Optional
Dispensed: Yes/No
Type: Storage/shipment
Logger ID: From Log or device
Description of deviation: From Log
Additional information: Optional
Write initials and date
Information from packs
Shipment no.: From Pack Slip

FASTEST

- The Temperature Excursion Report Form (TERF) - available in WebDCU™ Toolbox>Project Documents – submit for both storage and in-transit excursions

What's inside the FASTEST kit?

Dosing/compounding card

<u>Histidine Diluent box</u>
Containing two 5.2mL pre-filled syringes

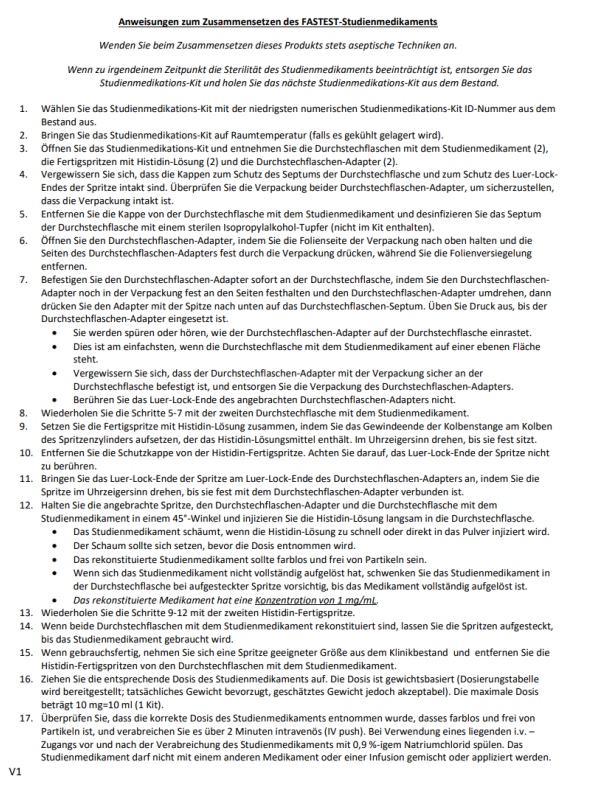
The DUN boxes containing histidine and rFVIIa will be referred to as kit components in WebDCU™.

<u>rFVIIa (Active or Placebo) box</u>
Containing two 5 mg vials of lyophilized drug

<u>13mm vial adapters</u>
Each kit must have <u>two</u> vial adapters

FASTEST

Kit Component Boxes: Dosing/compounding card



Anweisungen zum Zusammensetzen des FASTEST-Studienmedikaments

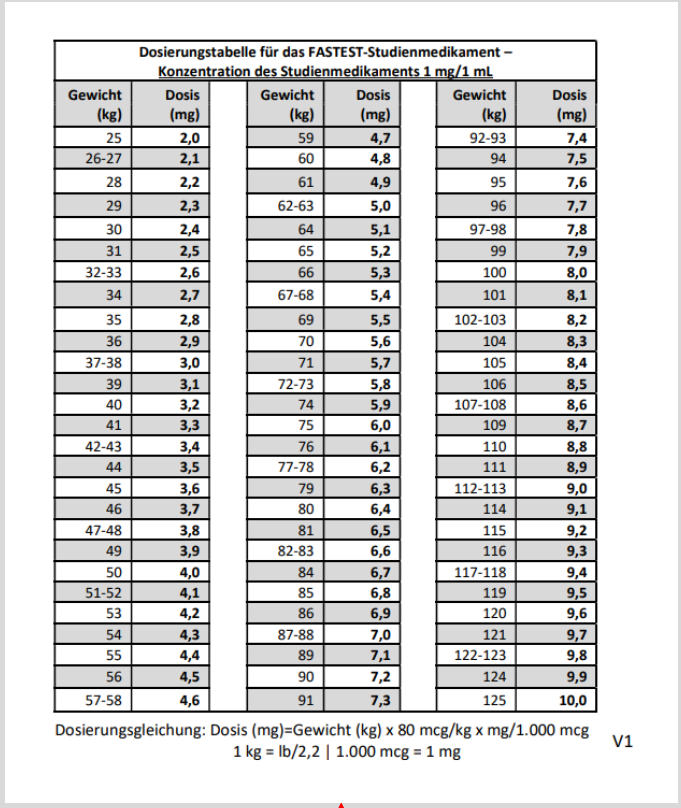
Wenden Sie beim Zusammensetzen dieses Produkts stets aseptische Techniken an.

Wenn zu irgendeinem Zeitpunkt die Sterilität des Studienmedikaments beeinträchtigt ist, entsorgen Sie das Studienmedikations-Kit und holen Sie das nächste Studienmedikations-Kit aus dem Bestand.

1. Wählen Sie das Studienmedikations-Kit mit der niedrigsten numerischen Studienmedikations-Kit ID-Nummer aus dem Bestand aus.
2. Bringen Sie das Studienmedikations-Kit auf Raumtemperatur (falls es gekühlt gelagert wird).
3. Öffnen Sie das Studienmedikations-Kit und entnehmen Sie die Durchstechflaschen mit dem Studienmedikament (2), die Fertigspritzen mit Histidin-Lösung (2) und die Durchstechflaschen-Adapter (2).
4. Vergewissern Sie sich, dass die Kappen zum Schutz des Septums der Durchstechflasche und zum Schutz des Luer-Lock-Endes der Spritze intakt sind. Überprüfen Sie die Verpackung beider Durchstechflaschen-Adapter, um sicherzustellen, dass die Verpackung intakt ist.
5. Entfernen Sie die Kappe von der Durchstechflasche mit dem Studienmedikament und desinfizieren Sie das Septum der Durchstechflasche mit einem sterilen Isopropylalkohol-Tupfer (nicht im Kit enthalten).
6. Öffnen Sie den Durchstechflaschen-Adapter, indem Sie die Folienseite der Verpackung nach oben halten und die Seiten des Durchstechflaschen-Adapters fest durch die Verpackung drücken, während Sie die Folienversiegelung entfernen.
7. Befestigen Sie den Durchstechflaschen-Adapter sofort an der Durchstechflasche, indem Sie den Durchstechflaschen-Adapter noch in der Verpackung fest an den Seiten festhalten und den Durchstechflaschen-Adapter umdrehen, dann drücken Sie den Adapter mit der Spitze nach unten auf das Durchstechflaschen-Septum. Üben Sie Druck aus, bis der Durchstechflaschen-Adapter eingesetzt ist.
   - Sie werden spüren oder hören, wie der Durchstechflaschen-Adapter auf der Durchstechflasche einrastet.
   - Dies ist am einfachsten, wenn die Durchstechflasche mit dem Studienmedikament auf einer ebenen Fläche steht.
   - Vergewissern Sie sich, dass der Durchstechflaschen-Adapter mit der Verpackung sicher an der Durchstechflasche befestigt ist, und entsorgen Sie die Verpackung des Durchstechflaschen-Adapters.
   - Berühren Sie das Luer-Lock-Ende des angebrachten Durchstechflaschen-Adapters nicht.
8. Wiederholen Sie die Schritte 5-7 mit der zweiten Durchstechflasche mit dem Studienmedikament.
9. Setzen Sie die Fertigspritze mit Histidin-Lösung zusammen, indem Sie das Gewindeende der Kolbenstange am Kolben des Spritzenzylinders aufsetzen, der das Histidin-Lösungsmittel enthält. Im Uhrzeigersinn drehen, bis sie fest sitzt.
10. Entfernen Sie die Schutzkappe von der Histidin-Fertigspritze. Achten Sie darauf, das Luer-Lock-Ende der Spritze nicht zu berühren.
11. Bringen Sie das Luer-Lock-Ende der Spritze am Luer-Lock-Ende des Durchstechflaschen-Adapters an, indem Sie die Spritze im Uhrzeigersinn drehen, bis sie fest mit dem Durchstechflaschen-Adapter verbunden ist.
12. Halten Sie die angebrachte Spritze, den Durchstechflaschen-Adapter und die Durchstechflasche mit dem Studienmedikament in einem 45°-Winkel und injizieren Sie die Histidin-Lösung langsam in die Durchstechflasche.
    - Das Studienmedikament schäumt, wenn die Histidin-Lösung zu schnell oder direkt in das Pulver injiziert wird.
    - Der Schaum sollte sich setzen, bevor die Dosis entnommen wird.
    - Das rekonstituierte Studienmedikament sollte farblos und frei von Partikeln sein.
    - Wenn sich das Studienmedikament nicht vollständig aufgelöst hat, schwenken Sie das Studienmedikament in der Durchstechflasche bei aufgesteckter Spritze vorsichtig, bis das Medikament vollständig aufgelöst ist.
    - *Das rekonstituierte Medikament hat eine Konzentration von 1 mg/mL.*
13. Wiederholen Sie die Schritte 9-12 mit der zweiten Histidin-Fertigspritze.
14. Wenn beide Durchstechflaschen mit dem Studienmedikament rekonstituiert sind, lassen Sie die Spritzen aufgesteckt, bis das Studienmedikament gebraucht wird.
15. Wenn gebrauchsfertig, nehmen Sie sich eine Spritze geeigneter Größe aus dem Klinikbestand und entfernen Sie die Histidin-Fertigspritzen von den Durchstechflaschen mit dem Studienmedikament.
16. Ziehen Sie die entsprechende Dosis des Studienmedikaments auf. Die Dosis ist gewichtsbasiert (Dosierungstabelle wird bereitgestellt; tatsächliches Gewicht bevorzugt, geschätztes Gewicht jedoch akzeptabel). Die maximale Dosis beträgt 10 mg=10 ml (1 Kit).
17. Überprüfen Sie, dass die korrekte Dosis des Studienmedikaments entnommen wurde, dasses farblos und frei von Partikeln ist, und verabreichen Sie es über 2 Minuten intravenös (IV push). Bei Verwendung eines liegenden i.v. – Zugangs vor und nach der Verabreichung des Studienmedikaments mit 0,9 %-igem Natriumchlorid spülen. Das Studienmedikament darf nicht mit einem anderen Medikament oder einer Infusion gemischt oder appliziert werden.

V1

Compounding instruction (German)



Dosierungstabelle für das FASTEST-Studienmedikament – Konzentration des Studienmedikaments 1 mg/1 mL

Gewicht (kg)	Dosis (mg)	Gewicht (kg)	Dosis (mg)	Gewicht (kg)	Dosis (mg)
25	2,0	59	4,7	92-93	7,4
26-27	2,1	60	4,8	94	7,5
28	2,2	61	4,9	95	7,6
29	2,3	62-63	5,0	96	7,7
30	2,4	64	5,1	97-98	7,8
31	2,5	65	5,2	99	7,9
32-33	2,6	66	5,3	100	8,0
34	2,7	67-68	5,4	101	8,1
35	2,8	69	5,5	102-103	8,2
36	2,9	70	5,6	104	8,3
37-38	3,0	71	5,7	105	8,4
39	3,1	72-73	5,8	106	8,5
40	3,2	74	5,9	107-108	8,6
41	3,3	75	6,0	109	8,7
42-43	3,4	76	6,1	110	8,8
44	3,5	77-78	6,2	111	8,9
45	3,6	79	6,3	112-113	9,0
46	3,7	80	6,4	114	9,1
47-48	3,8	81	6,5	115	9,2
49	3,9	82-83	6,6	116	9,3
50	4,0	84	6,7	117-118	9,4
51-52	4,1	85	6,8	119	9,5
53	4,2	86	6,9	120	9,6
54	4,3	87-88	7,0	121	9,7
55	4,4	89	7,1	122-123	9,8
56	4,5	90	7,2	124	9,9
57-58	4,6	91	7,3	125	10,0

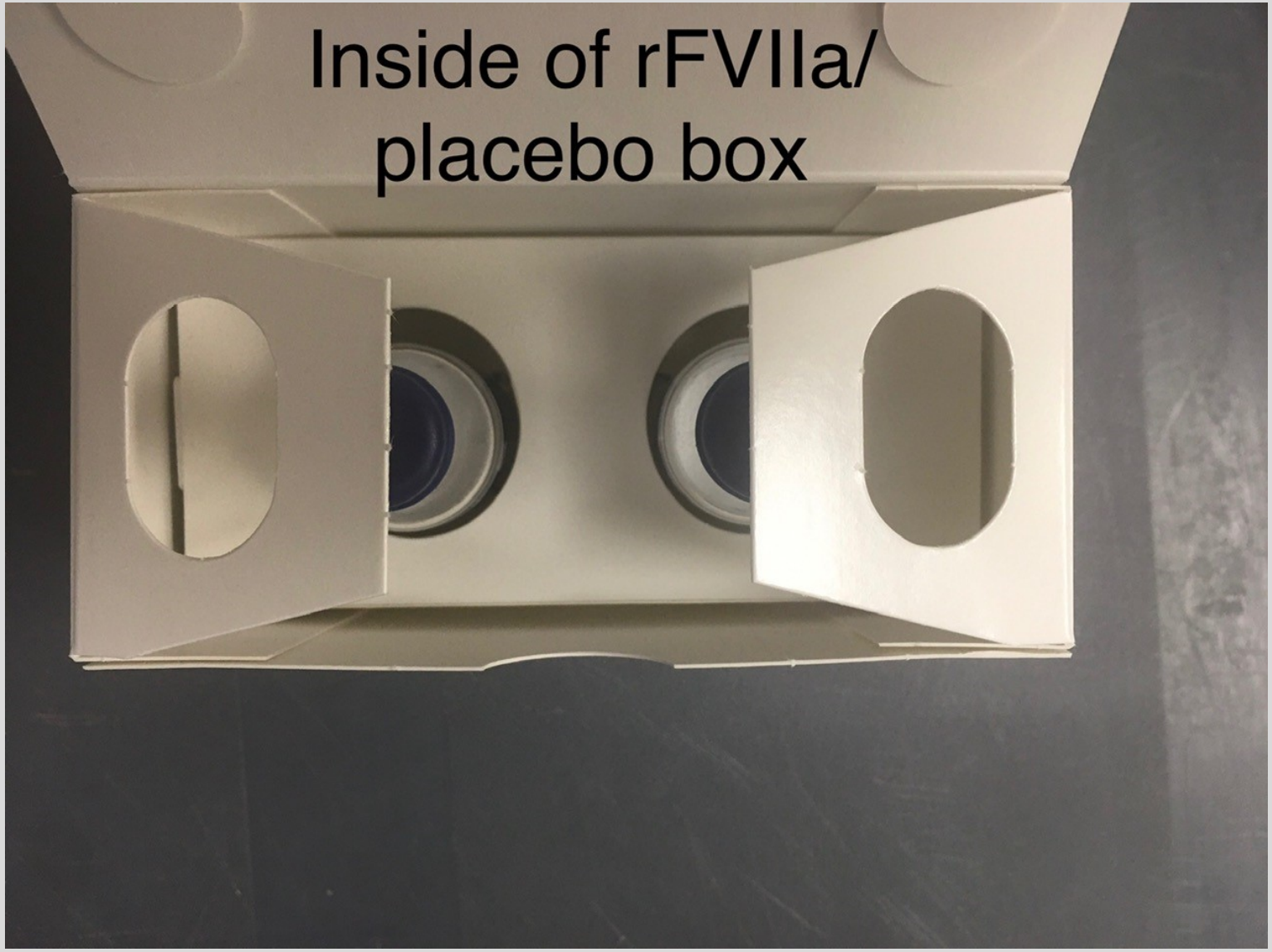
Dosierungsgleichung: Dosis (mg)=Gewicht (kg) x 80 mcg/kg x mg/1.000 mcg
1 kg = lb/2,2 | 1.000 mcg = 1 mg

V1

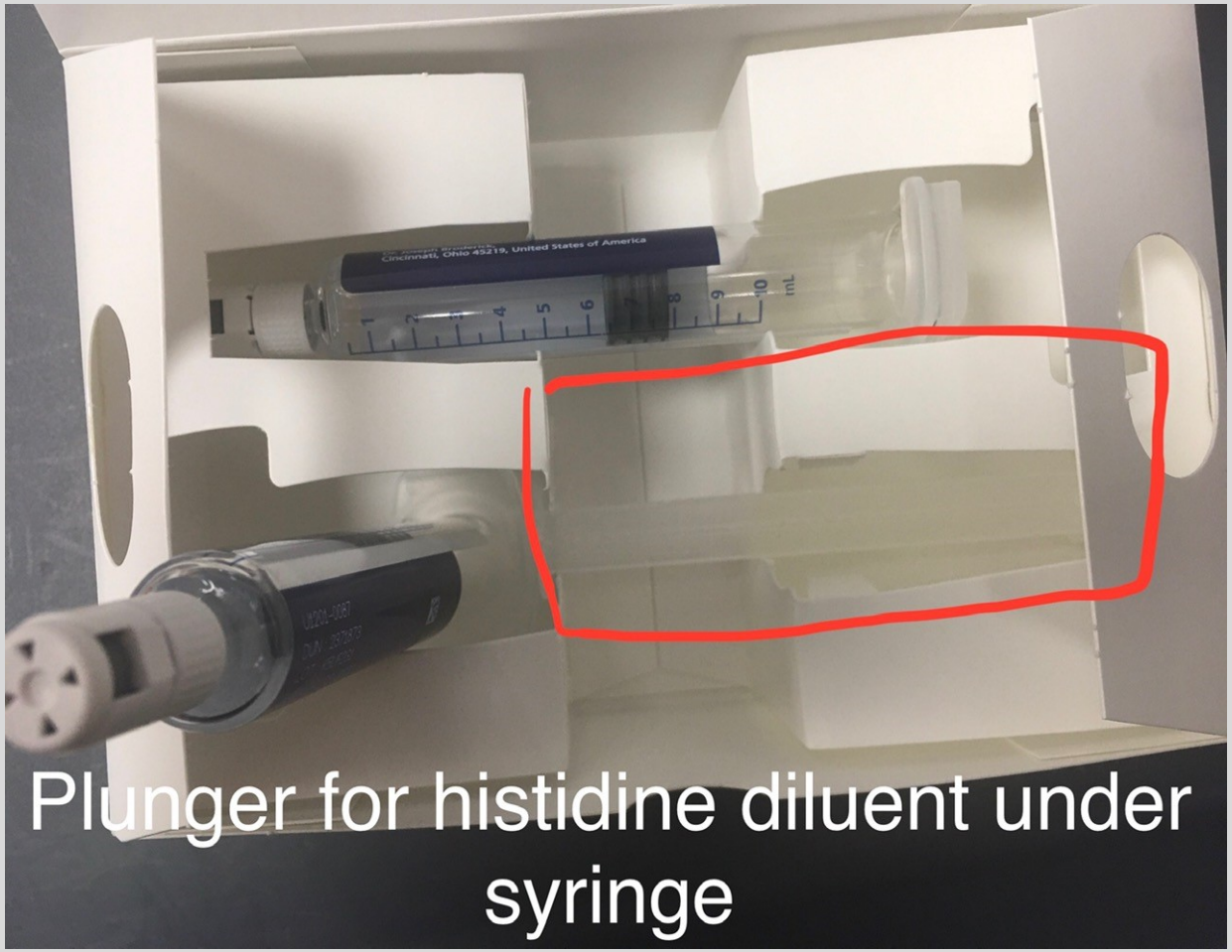
Dosing chart (German version)

- **Card (folded DIN-A4) in German language added to each kit**
- Additional 3 cards (folded DIN-A4) in English, Spanish, Catalan added to each kit

Inside the shipment from Novo Nordisk-Inside the rFVIIa/placebo DUN Box



Inside the shipment from Novo Nordisk-Inside the Histidine DUN Box



Accountability & Chain of Custody

- CPS with two enrolling locations with four kits; the CPS can determine how many study drug kits to store for each enrolling location; WebDCU™ will not provide this information
- It is recommended to keep **two kits at each enrolling location**, so a back-up kit is available, if needed.
- CPSs will be responsible to complete the chain of custody form each time a study drug kit is transferred internally from one location to another.
- Chain of Custody and Accountability logs serve as a tracking document to track the investigational product from the time it leaves the manufacturer until the time it is used by a subject, destroyed, or returned back to the European Central Pharmacy

Don’t break the chain!

- CPSs are required to maintain study drug accountability records and temperature monitoring logs
  - CPSs may use their institution’s electronic inventory system or use the provided paper logs (WebDCU™ Toolbox>Project Documents)

Drug Accountability

Investigational product (IP) Drug Accountability Log
Protocol Number: U1111-1201-0087

Site Name:
Site Number:
Principal Investigator:

Overall inventory on site				Subject level drug accountability						Drug destruction	
Date received	Total # of kits received	Balance of drug kits in stock	Site personnel (initials/date)	Pt initials	Date dispensed	Kit code	Total volume prepared (mL)	Total volume administered (mL)	Dispenser (initials/date)	# of vials destroyed	Site personnel (initials/date)

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FASTEST

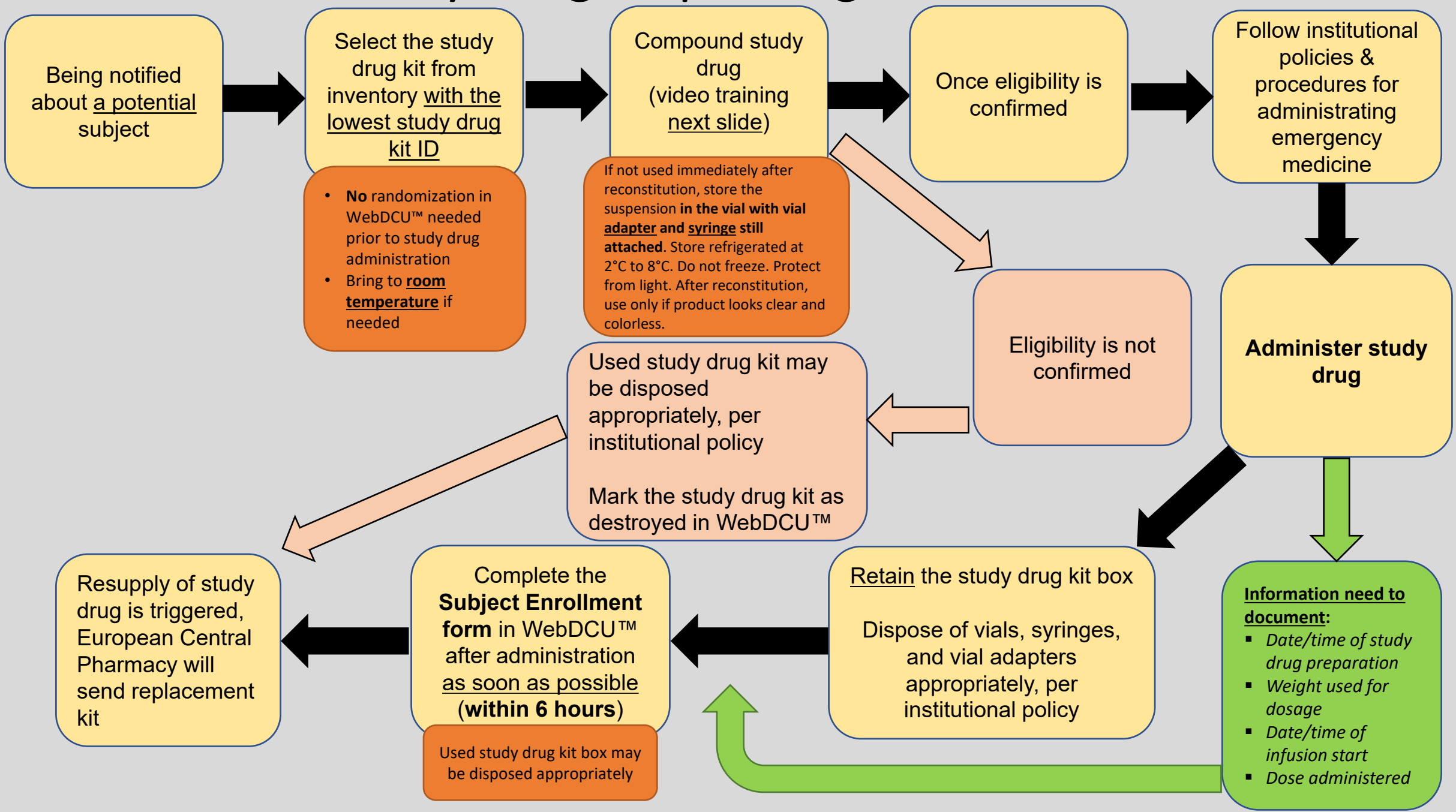
Chain of Custody

Investigational product (IP) Chain of Custody
Protocol Number: U1111-1201-0087

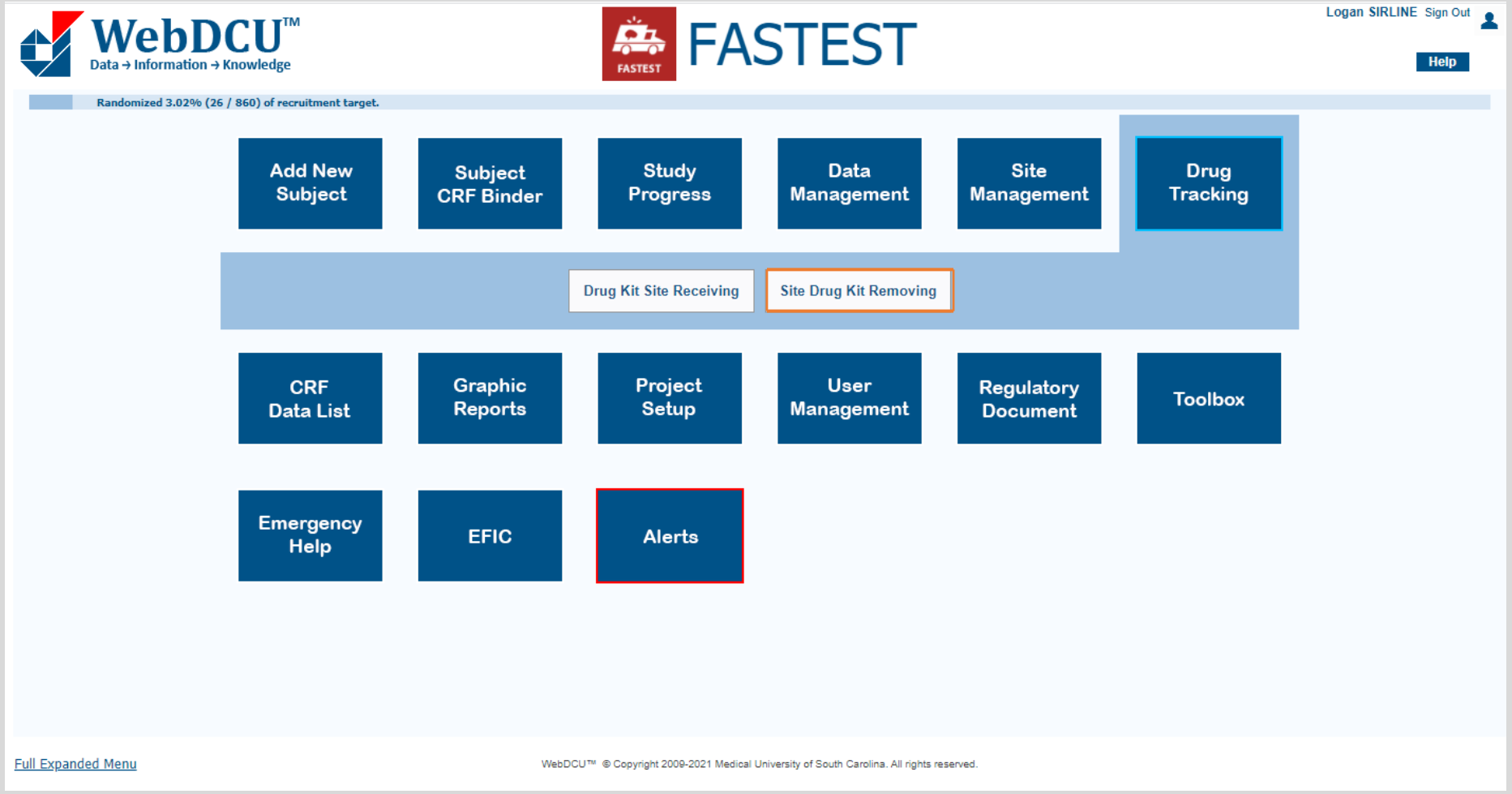
Instructions: *Any exchange of FASTEST Kits should be documented on this form*

Transition From *(Location of Medication Storage)*	**Transition To** *(Location of Medication Storage)*	**Date/Time**	**Received by (initials)**	**# of Kits**	**Kit Code(s)**	**The Study Kit/s is/are received in good condition (initials/date)**

Study Drug Dispensing Workflow



Drug Kit Removing



Compounding Video

Please review and refer to the pharmacy compounding video for visual demonstration:
https://dcu.musc.edu/campus/ProjectTraining/FASTESTPharmacyCompounding.mp4

IMPORTANT

- The pre-filled glass syringe is **compatible with a standard Luer-lock connector**

- However, some needleless connectors for intravenous catheters are incompatible with the glass diluent syringes (for example, certain connectors with an internal spike, such as Clave®/MicroClave®, InVision-Plus®, InVision-Plus CS®, InVision-Plus® Junior®, Bionector®), and their use can damage the connector and affect administration.

- To administer study drug through incompatible needleless connectors, withdraw reconstituted product into a standard 10 mL sterile Luer-lock plastic syringe.

Study Drug Requests

- WebDCU™ study drug shipment requests will automatically be sent to the European Central Pharmacy when:
- Site released to receive study drug
- Subjects are randomized (complete Subject Enrollment form in WebDCU™ within **6 hours** of drug administration)
- Study drug is damaged/expired
  - Drug request will be sent to the European Central Pharmacy 14 days prior to kit expiration

Study Drug Kit Expiration

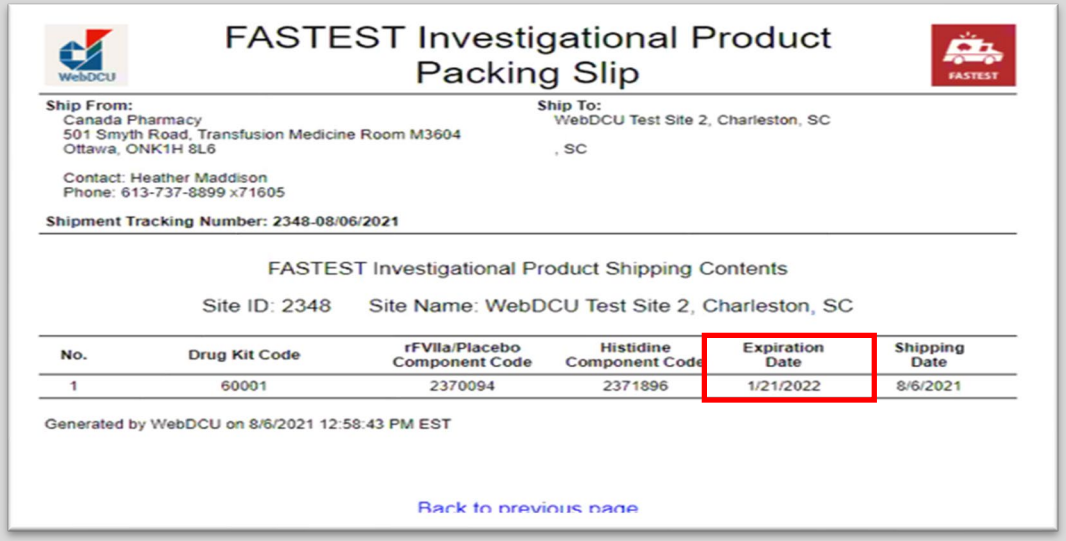
Study drug kit expiration dates are available in 3 locations:

- Study drug kit labels
- FASTEST study drug packing slip
- WebDCU™ (Drug Tracking Tab>Site Drug Kit Removing)

CPSs will receive emails from WebDCU™ and the European Central Pharmacy when kits are nearing their expiration

Emails will contain instructions on how to handle expiring kits and when to expect replacement kits

Replacement kits will be sent before current inventory expirations to prevent CPSs from running out of study drug inventory



FASTEST Investigational Product Packing Slip

Ship From:
Canada Pharmacy
501 Smyth Road, Transfusion Medicine Room M3604
Ottawa, ONK1H 8L6

Contact: Heather Maddison
Phone: 613-737-8899 x71605

Ship To:
WebDCU Test Site 2, Charleston, SC
, SC

Shipment Tracking Number: 2348-08/06/2021

FASTEST Investigational Product Shipping Contents

Site ID: 2348 Site Name: WebDCU Test Site 2, Charleston, SC

No.	Drug Kit Code	rFVIIa/Placebo Component Code	Histidine Component Code	Expiration Date	Shipping Date
1	60001	2370094	2371896	1/21/2022	8/6/2021

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FASTEST

Study Drug Destruction & Return

CPSs should follow their institutional policy regarding drug destruction protocol

The European Central Pharmacy can accept returns for destruction if a CPS's institutional policy requires returning the damaged or expired drug kits

Follow the steps below to return study drug to the European Central Pharmacy

Study Drug Return Form must be completed and returned with the shipment

Available on WebDCU™ - Toolbox>Project Documents

Returns should be addressed and shipped to the European Central Pharmacy via the CPSs preferred postal carrier

Return cost will be at the expense of the CPS

Package tracking information must be provided to European Central Pharmacy via email

Temperature monitoring is NOT required for returns

Subject identifiers must be removed from returns

Study Drug Destruction & Return

Instructions to the Pharmacist/Designee:

1. Type or handwrite clearly all information.
2. Complete all sections (except *European Central Pharmacy Use Only* section).
3. Print this form (if needed).
4. Sign and date this form.
5. Keep a copy of form for your records.
6. Enclose this form with study products and return via preferred shipping method to the EuropeanCentral Pharmacy.
7. Pack study products properly to prevent breakage and/or leakage.

Study Drug Return Form

Protocol Number: U1111-1201-0087

FASTEST

Return to:
European Central Pharmacy
Heidelberg University Hospital
Clinical Trials
Im Neuenheimer Feld 670
69120 Heidelberg
Germany
Phone: +49-6221-56-32827
Fax: +49-6221-56-5413
Email: v-apoth.studien@med.uni-heidelberg.de

Site Name	Site Number
Designee/Pharmacist Name	

Protocol Number	Kit Code	Full	Partial	Manufacturer	Lot Number	Comment(s)

Pharmacy/Site Mailing Address	Designee/Pharmacist Name	Contact Phone Number
	Designee/Pharmacist Signature	Date

European Central Pharmacy Use Only

Protocol Number/Study Product Name	Date Processed	Signature of Reviewing Official

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PREVENTION | TREATMENT | RECOVERY

FASTEST

When you think about **FASTEST** remember …….

- Prepare study drug as **FAST** as you can (prior to study drug administration, no randomization in WebDCU™ needed)

- Complete the Subject Enrollment form in WebDCU™ as **FAST** as possible (within 6 hours post study drug administration) for …

- European Central Pharmacy to resupply you with study drug as **FAST** as they can.

Questions?

Please visit WebDCU™ for a copy of the FASTEST Study Drug Manual of Procedures for Europe

Toolbox>Project Documents