

gestione del farmaco sperimentale

Elisa Perfetti 4 novembre 2011

Temi di discussione

ARGOMENTI DA TRATTARE

ricezione del farmaco sperimentale

contabilità del farmaco sperimentale

conservazione del farmaco sperimentale

distruzione del farmaco sperimentale

Medicinale sperimentale

(IMP, *Investigational Medicinal Product*):

❖ Forma farmaceutica

di un principio attivo o di un placebo saggiato come medicinale sperimentale o come controllo in una sperimentazione clinica

❖ Prodotti con AIC

preparati e utilizzati in forme diverse da quelle autorizzate, utilizzati per indicazioni non autorizzate, per ottenere informazioni aggiuntive sulle forme autorizzate, utilizzati come controllo

Ricezione

**SECONDO LA NORMATIVA CORRENTE
LA RICEZIONE DEL FARMACO SPERIMENTALE
PUÒ AVVENIRE SOLO ALLA FARMACIA
OSPEDALIERA**

- dopo l'attivazione del centro
- verifica integrità



integrità

- CONTENUTO
- TEMPERATURA



integrità

- CONTENUTO

Acknowledgement of Receipt

Upon receipt of the shipment, please inspect and verify the contents and conditions of the shipment.

Please sign and email this form to  Drug Supply Office (Email:).

Maintain the original form in your files.

All above supplies were received in good conditions: yes no

Discrepancies _____

Name: _____ Signature/Date: _____

**se qualcosa
va storto**

verifica integrità



gestione dei farmaci sperimentali

Complaint form

Product (please tick)	
<input type="checkbox"/> Palbociclib, 23 capsules per bottles strength: <input type="checkbox"/> 75 mg <input type="checkbox"/> 100 mg <input type="checkbox"/> 125 mg	<input type="checkbox"/> Fulvestrant, 250mg/5ml, syringes, solution for injection
Lot no.: Expiry date: Quantity of affected bottles/syringes:	
Site name : [Redacted]	Address :
Investigator :	
Incident description:	
Date & time the incident was noticed: (dd/mm/yyy)	
Product administered to a patient: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Enclosure: <input type="checkbox"/> Photography <input type="checkbox"/> Other:	
Name, function and e-mail of person completing this form:	
Date (initial form completion): (dd/mm/yyy)	

Please send the completed Complaint Notification Form to [Redacted]

Complaint details for the products listed above have been evaluated.

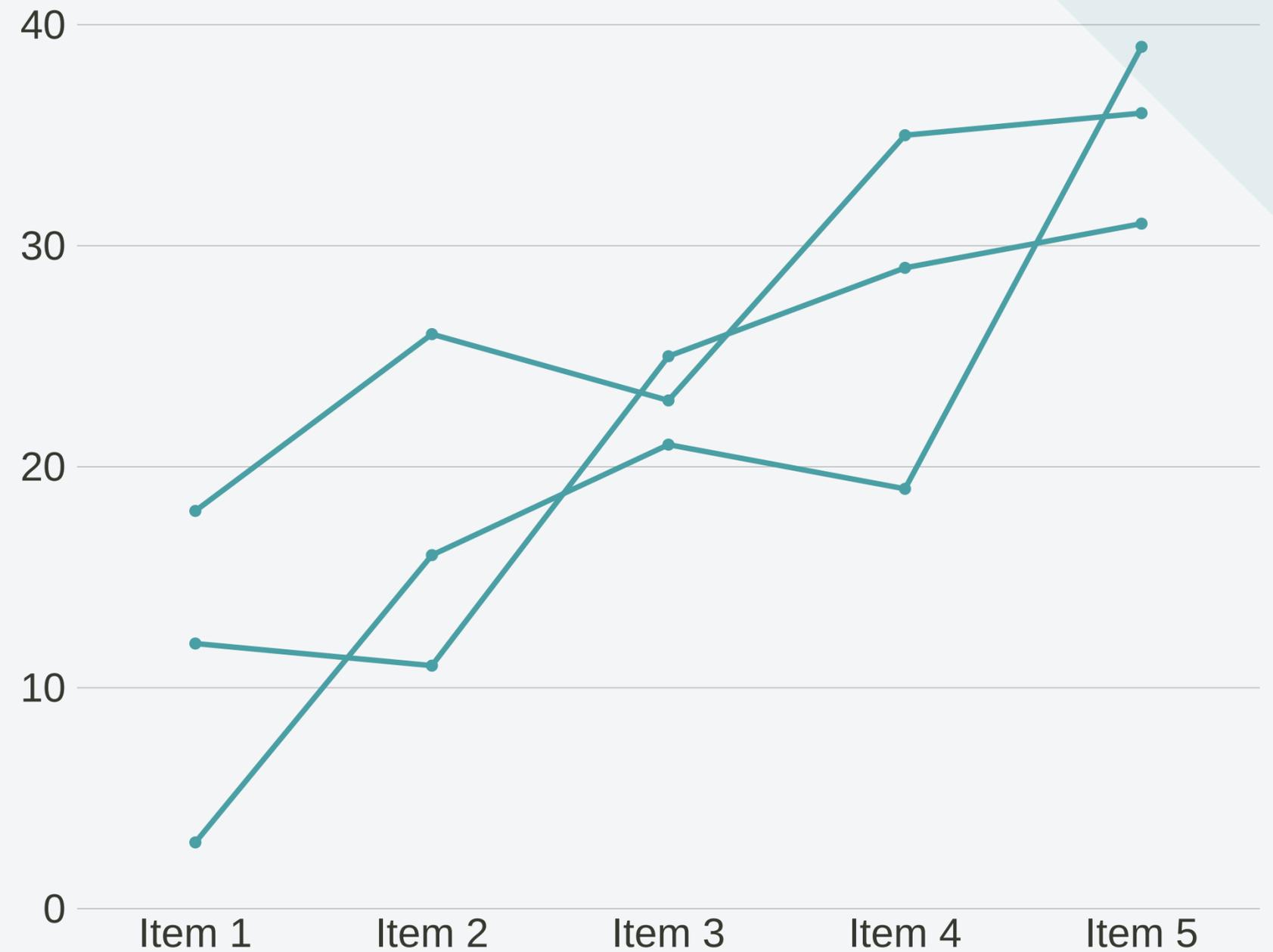
Please be advised that:

- All products are suitable for continued use
- All products are **not** suitable for further dispensation. Please remove supplies from available inventory and work with your Site Manager to have supplies destroyed.
- Other (Please see details below):

Assessment completed by: _____ Date _____

ricezione ok

verifica temperatura di trasporto



TEMPERATURE MONITORED SHIPMENT INSPECTION INSTRUCTIONS FOR TEMPTALE (V3, 27-Oct-2015)



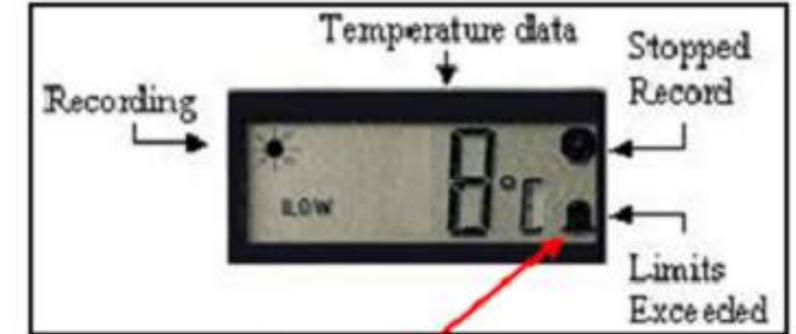
1. Delivery



2. Un-pack and locate device



3. Press and hold the STOP button (1 to 3 seconds) until following icon appears



4. Examine the screen for an icon in the shape of a bell in the lower right hand corner of the display.



5a. If the screen has a bell shaped icon, please quarantine the drug at the product label storage conditions.
5b. If the screen has no bell shaped icon, medication is acceptable for use.



6. Connect the USB plug to your Computer



7. The monitor will automatically begin creating
1. an Adobe® PDF report
2. a ".ttx" data file (this is a non human readable file)
Both files will appear on your computer

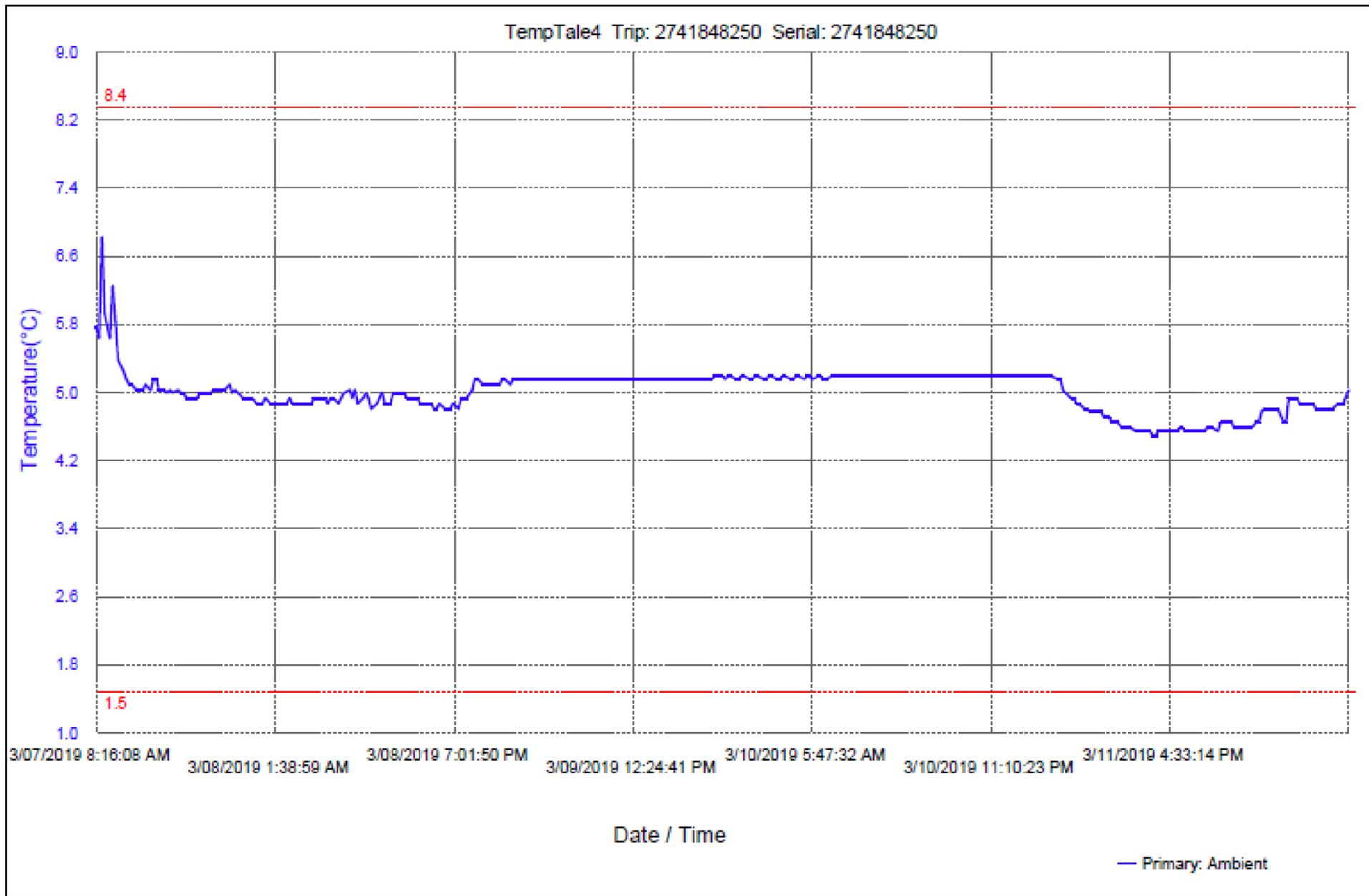


8. In any case email BOTH files (1. and 2.) to:
[drugsupply@\[REDACTED\]](mailto:drugsupply@[REDACTED])
Please indicate ALARM (5a.) or NO ALARM (5b.) the protocol and site number as email subject.

NB: The device must be disposed of locally in the same manner as electronic goods, due to a battery inside. Please do NOT return any TempTale to the sender by courier.

Low Extreme: 4.5 °C @ 3/11/2019 3:26:08 PM	Low Alarm Time Below: 0 sec	High Alarm Time Above: 0 sec
High Extreme: 6.8 °C @ 3/07/2019 8:56:08 AM	Longest Time Below: 0 sec	Longest Time Above: 0 sec
Mean ± Standard Deviation: 5.0 °C ± 0.3 °C	Degree Minutes Below: 0.0 °C min	Degree Minutes Above: 0.0 °C min
Mean Kinetic Temperature: 5.0 °C	Number Events Below: 0	Number Events Above: 0
Activation Energy: 83.144 kJ/mol	Triggered:	Triggered:

Originator Notes



TEMPERATURE Excursion form

IBCSG center code: _____

Study Medication
Palbociclib Lot Number(s): _____
strength: 75 mg 100 mg 125 mg
Excursion date: ____/____/____ Max. Min. Temperature reached: _____ °C
Duration of Excursion (hours): _____ h _____ mn Not Known
Cause of the temperature excursion:

Has the cause been fixed?
 yes (how was it fixed?) _____
 no (why was it not fixed?) _____
Did the concerned Study Medication have a temperature deviation before?
 yes (please specify in below) no

Completed by: _____ Date: ____/____/____
Printed name

Signature

Send completed Temperature Excursion Form to: _____

Completed by IBCSG:

Action to be taken: The study agent(s) mentioned above can be dispensed to study subjects
 The study agent(s) mentioned above **MUST NOT** be dispensed to study subjects and should be destroyed

Additional Comments:

Approved by: _____ Date: _____
Printed name

Signature



quando **non è la**
farmacia
a gestire il farmaco
sperimentale
questo viene inviato al
reparto del PI

delegation log

Principal Investigator: _____ Center Name: _____
 Job Title: _____ Center No: _____

Study Personnel, whose signatures and initials appear below, are authorized to perform the following study tasks indicated by codes "A" to "J", on my behalf within the dates indicated. I confirm that they are qualified and appropriately informed about the trial.

A* = finally determine eligibility	D = make CRF entries/corrections	H = _____
B* = obtain informed consent	E = sign CRFs	I = _____
C = perform key trial measurements	F = dispense medication	J = _____
	G = unblinding/breaking the blind	

* Functions marked with an asterisk are considered the sole responsibility of the Principal Investigator, but may be delegated to Co-investigators. Codes H, I and J may be used to specify other tasks or any of the above functions in which study personnel assist the Investigator.

Principal Investigator

Printed Name	Signature	Initials	Date
_____	_____	_____	_____

Participating Center personnel (Please use BLOCK CAPITALS)	Authorization code(s) (see above)	Signature	Initials	Date Authorized From/To + Principal Inv.'s Initials
Name: _____ Job Title: _____ Function: _____				From: _____ To: _____ PI Init: _____
Name: _____ Job Title: _____ Function: _____				From: _____ To: _____ PI Init: _____

L'importanza della tracciabilità

➔ 4.6.2 Nei casi in cui sia consentito/richiesto, lo sperimentatore/istituzione può/deve delegare alcuni o tutti i compiti dello sperimentatore/istituzione per la affidabilità del/i prodotto/i in studio nella/e sede/i dello studio **ad un farmacista** o ad un'altra persona competente che sia sottoposto alla supervisione dello sperimentatore/istituzione.

LA RICEZIONE DEVE AVVENIRE IN FARMACIA

➔ 4.6.3 Lo sperimentatore/istituzione **e/o il farmacista** od altra persona competente, designato dallo sperimentatore/istituzione, *deve conservare la documentazione relativa alle consegne e all'inventario del prodotto nella sede dello studio, all'uso del prodotto da parte di ciascun soggetto e alla restituzione allo sponsor o allo smaltimento alternativo del/i prodotto/i non utilizzato/i. Queste registrazioni devono comprendere le date, le quantità, i numeri di lotto o di serie, le date di scadenza (se è il caso) ed i numeri di codice unici assegnati al/i prodotto/i in esame ed ai soggetti dello studio.....*



Obblighi del Centro

- Usare i farmaci in studio esclusivamente secondo quanto specificato nel protocollo approvato
- Seguire le istruzioni per la preparazione del farmaco e per la sua somministrazione
- Seguire le istruzioni per la distribuzione/consegna al paziente
- Seguire le istruzioni per la contabilità del farmaco
- Conoscere il/i farmaco/i sperimentale/i, uso, informazioni di sicurezza/efficacia, profilo di tollerabilità, tossicità, farmacocinetica, modalità di assegnazione (randomizzazione, numerazione, pacco paziente), dosi, regimi posologici, procedure di preparazione, modalità di assunzione, terapie concomitanti ammesse e non, gestione delle tossicità
- Conoscere le condizioni di conservazione del farmaco

Prima dell'inizio dello studio è importante definire i processi legati alla gestione del farmaco, la modulistica del farmaco e la compilazione della stessa

Assegnazione del trattamento

manuale



Assegnazione del trattamento



sistema
informatizzato



GESTIONI DI IMP

IVRS : INTERACTIVE **V**OICE **R**ESPONSE **S**YSTEM

IWRS: INTERACTIVE **W**EB **R**ESPONSE **S**YSTEM

RTSM: **R**ANDOMIZATION AND **T**RIAL **S**UPPLY
MANAGEMENT

Multi-site, multi-country clinical trials can be difficult to manage.

Both services can be accessed from any location worldwide.

Both allow study administrators and investigators to securely interact with the study database



... NON SOLO IMP

BENEFITS

IVRS and IWRS have gained wide acceptance because they provide real-time benefits in :

- Patient Randomisation,
- drug assignment and inventory management,
- study blinding,
- reporting,
- systems integration
- and low costs

Facilitare la gestione dei farmaci

ERRATA ASSEGNAZIONE DI FARMACI

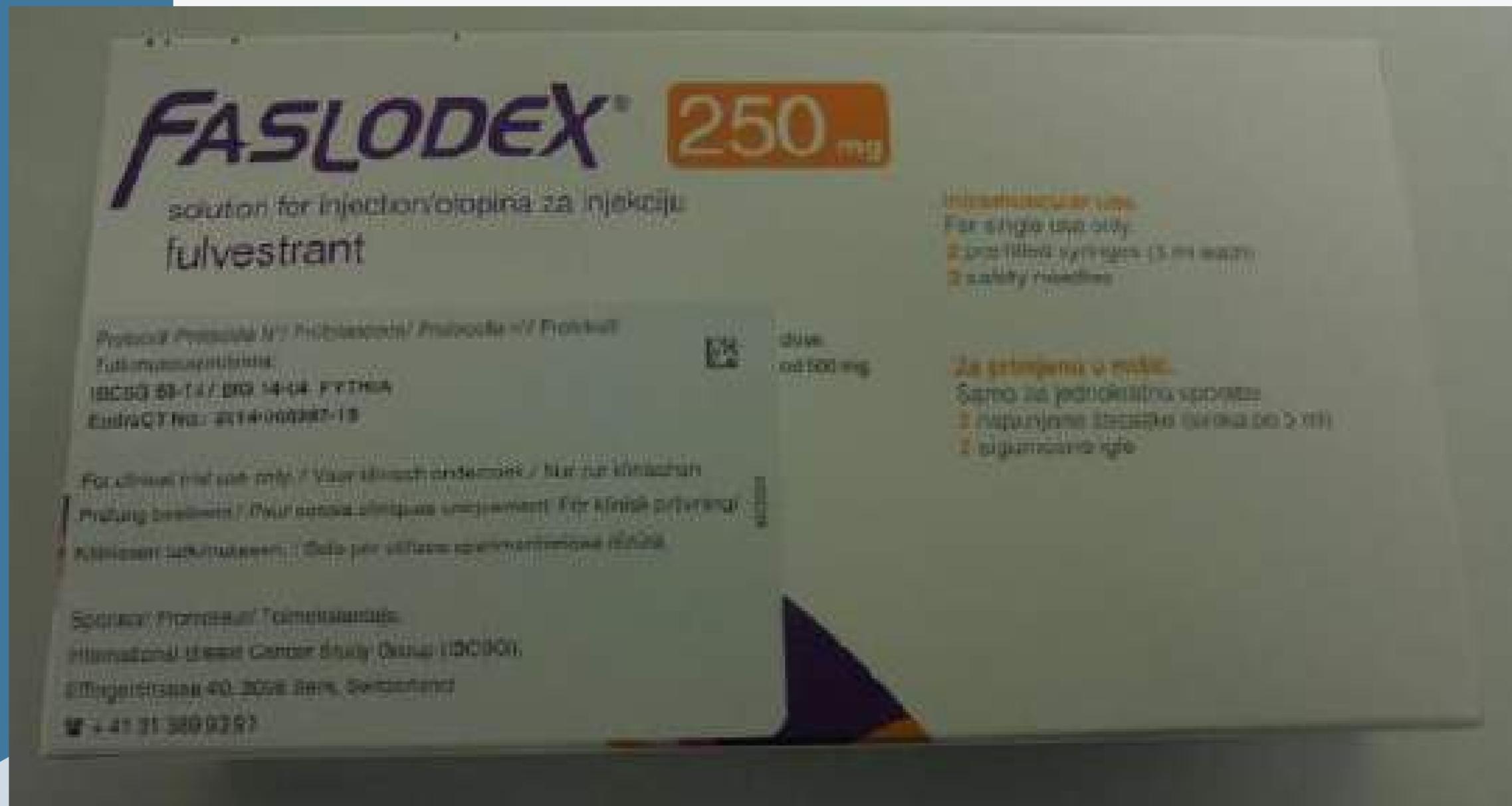
QUANTITATIVO INSUFFICIENTE DEI FARMACI



I CINQUE GIUSTI

Un uso razionale dei farmaci implica
il farmaco giusto somministrato
nella dose giusta per la via giusta al
momento giusto al paziente giusto.

FARMACO GIUSTO: COMMERCIALE O SPERIMENTALE?



FARMACO GIUSTO DOSE GIUSTA



MOMENTO GIUSTO PAZIENTE GIUSTO

Calendario

PAZIENTE	PROTOCOLLO	DATA	NOTE
	CARTOON	19-ott-21	visita x II ciclo
	CARTOON	19-ott-21	C6g1
	FATA GIM 3	20-ott-21	ore 9.30 fup
	FATA GIM 3	20-ott-21	ore 10 fup
	FUCSAM	21-ott-21	saltato precedente fup x covid - fa esami e questionario VISITA ore 12
	GWAS	21-ott-21	V. quando visita dopo chirurgia/ solo sopravvivenza - no questionario - progressione di malattia
	FUCSAM	22-ott-21	fup
	CARTOON	26-ott-21	C6g8 viene per prelievo ore 8 Consegnare diario del VI ciclo
	CARTOON	26-ott-21	sospeso lonsurf attivata capecitabina.Fup
	FUCSAM	27-ott-21	ultima visita da studio! H 14.30 amb C
	FUCSAM	27-ott-21	ultima visita da studio h. 14.30
	FATA GIM 3	27-ott-21	sopravvivenza, cercare dati in galileo o vue motion
	Aggiornamento STUDI	29-ott-21	fucsam gwas ermes impassion fata acis echos
	ERMES	29-ott-21	Inviare lettera per restituzione blocchetti studio Ermes. Vedi faldone n°2 sez. 6.5 c'è lettera da inviare
	CARTOON	29-ott-21	III ciclo, Fotocopiare ECG
	CARTOON	2-nov-21	In attesa di discussione GIC dopo TC. Verificare se continua farmaco
	AVETRIC	2-nov-21	Visita oggi ore 10
	FATA GIM 3	2-nov-21	sopravvivenza cercare in galileo e vuemotion
	APPALACHES	4-nov-21	visita. Ha iniziato RT verificare quando inizia Palbociclib e inserire RT a posteriori in CRF in Cycle 1
	MITO 25.1	4-nov-21	ciclo 3
	SAMANTHA	4-nov-21	ritirare referti vari + QoL

COSA DOCUMENTARE

COME

Drug Accountability Form

Center Name:

[REDACTED]		Study	[REDACTED]					
------------	--	--------------	------------	--	--	--	--	--

Drug Accountability Form for: [REDACTED] ®) / 30 tablets

Study Medication Supplier: [REDACTED] *Local Investigator:*

	Movement specification (incl. Patient ID, Supply ID, Destruction ID)	Date	Lot number	Expiry date	Entry (n° Packages)	Exit (n° Packages)	Stock (n° Packages)	Recorder's initials	Comments
1	first drug supply	04/10/2021	AB12345	ott-22	4	0	4	ep	
2	patient ID 001	04/11/2021	AB12345	ott-22	0	2	2		
3									
4									
5									
6									

CONTABILITA' PER FARMACO

Drug Dispensing Log Palbociclib

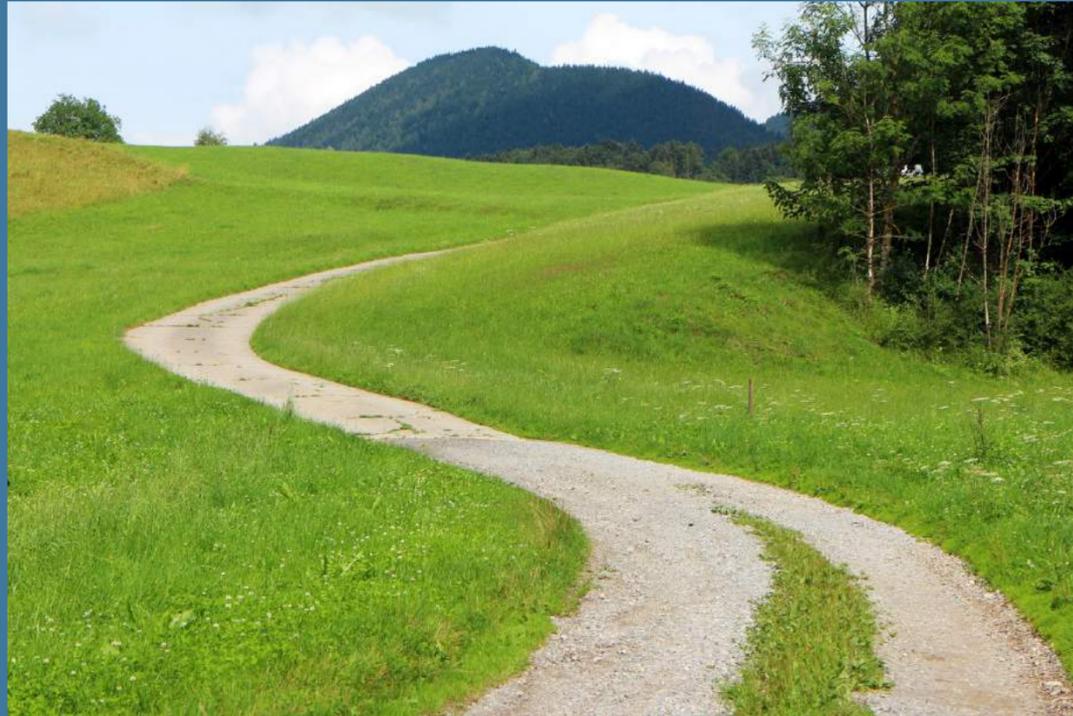
Protocol		Center Name:	
Study Medication:		IBCSG Center Code:	
Study Medication Supplier:		Principal Investigator Name:	

Patient ID:	
-------------	--

Qty of Bottles	Dose	Visit #	Dispensation of Palbociclib			Return of Palbociclib			Monitor initials / date
			date dispensed	number of capsules dispensed	information completed by (date&initials)	date returned	number of capsules returned	information completed by (date&initials)	
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg <input type="checkbox"/> 125mg								
	<input type="checkbox"/> 75mg <input type="checkbox"/> 100mg								

CONTABILITA' PER PAZIENTE

**L'INTERO PERCORSO DEL FARMACO:
SPEDIZIONE E ARRIVO IN FARMACIA**



INTEGRITA' E SCADENZA

CONSERVAZIONE

PREPARAZIONE

SOMMINISTRAZIONE

CONSEGNA AL PAZIENTE

RESO: COMPLIACE PAZIENTE

RESUPPLY

Ordering organisation / person:

Name	Elisa Perfelli
Title	Pharmacist/ DM
Email	ricerca@aslbi.piemonte.it
Phone	0039/015/15157522

Fisher Component:	Item Description:	Quantity per item (bottles)
Ship ambient Monday to Friday		
(PD-0332991-00 = Palbociclib)		
Shortest exp. date to be selected	PD-0332991-00 75mg 23 count Labeled Bottle	0
Shortest exp. date to be selected	PD-0332991-00 100mg 23 count Labeled Bottle	3
Shortest exp. date to be selected	PD-0332991-00 125mg 23 count Labeled Bottle	0

Fisher Component:	Item Description:	Quantity per item (vials)
Ship 2-8°C Monday to Wednesday		
Shortest exp. date to be selected	Pack cont. Fulvestrant 250mg/ 5ml 2 x pre-filled Syringes Labeled	

Complete delivery address:

Site name	Ospedale degli Infermi ASLBI
Site #	6101
Inv. First Name / Last Name	
Attention to	
Title	Pharmacist
Department	Farmacia Ospedaliera ASLBI
Address 1	Via dei Ponderanesi 2
Address 2	



STOCCAGGIO E CONSERVAZIONE DEL FARMACO SPERIMENTALE

IN LUOGO E SPAZIO ADEGUATI: AD ES
ARMADI SOTTO CHIAVE

ACCESSO RISTRETTO A PERSONALE
AUTORIZZATO

BEN SEPARATO DAI FARMACI DEL
REPARTO/IN COMMERCIO/AA STUDI

BEN IDENTIFICABILE

PREVEDERE AREE PER LA QUARANTENA

TEMPERATURA CONTROLLATA



DESTRUCTION FORM

Protocol		Center Name:	
Study Medication:		Center Code:	
Study Medication Supplier:		Principal Investigator Name:	

Study Medication	Lot number	Expiry date	Quantity destroyed	Date of destruction (dd/mm/yyyy)	Destruction ID (if applicable)	Reason for destruction (please tick)	Comments
[REDACTED]						<input type="checkbox"/> expired <input type="checkbox"/> damaged <input type="checkbox"/> other: _____	
[REDACTED]						<input type="checkbox"/> expired <input type="checkbox"/> damaged <input type="checkbox"/> other: _____	
[REDACTED]						<input type="checkbox"/> expired <input type="checkbox"/> damaged <input type="checkbox"/> other: _____	
[REDACTED]						<input type="checkbox"/> expired <input type="checkbox"/> damaged <input type="checkbox"/> other: _____	
[REDACTED]						<input type="checkbox"/> expired <input type="checkbox"/> damaged <input type="checkbox"/> other: _____	

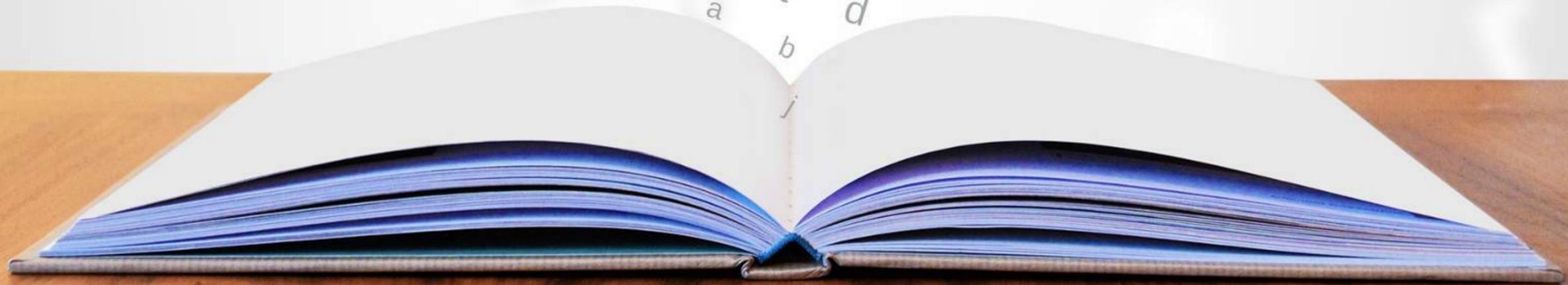
Pharmacist/Person responsible for drug handling:

Date:

Signature:

Please keep the original drug destruction certificates for your records and send a copy to [drugsupply@\[REDACTED\]](mailto:drugsupply@[REDACTED])

Pharmacy manual



Esempio di Pharmacy Manual studio in cieco

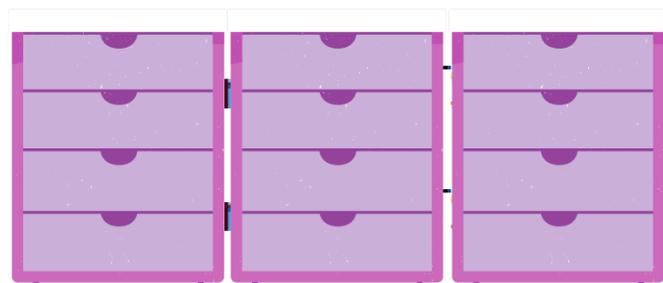


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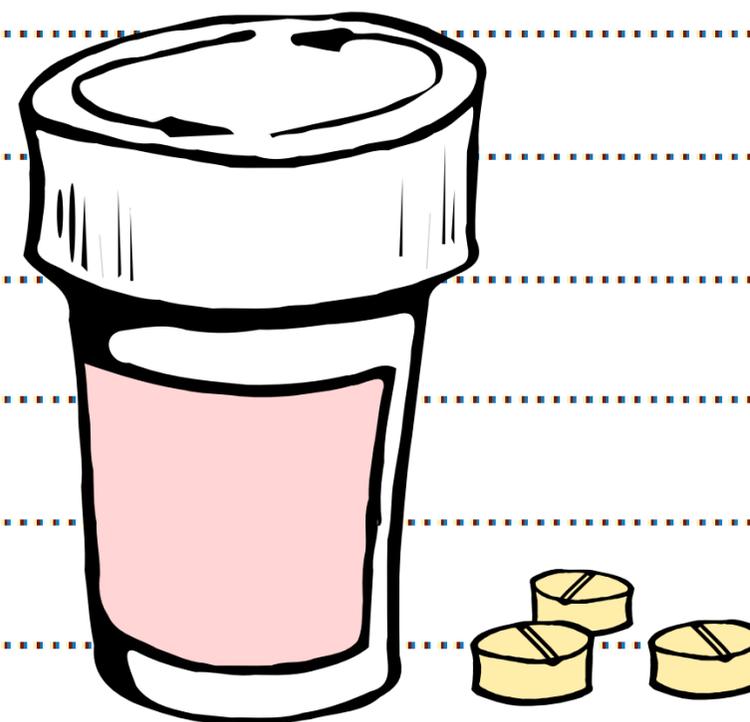
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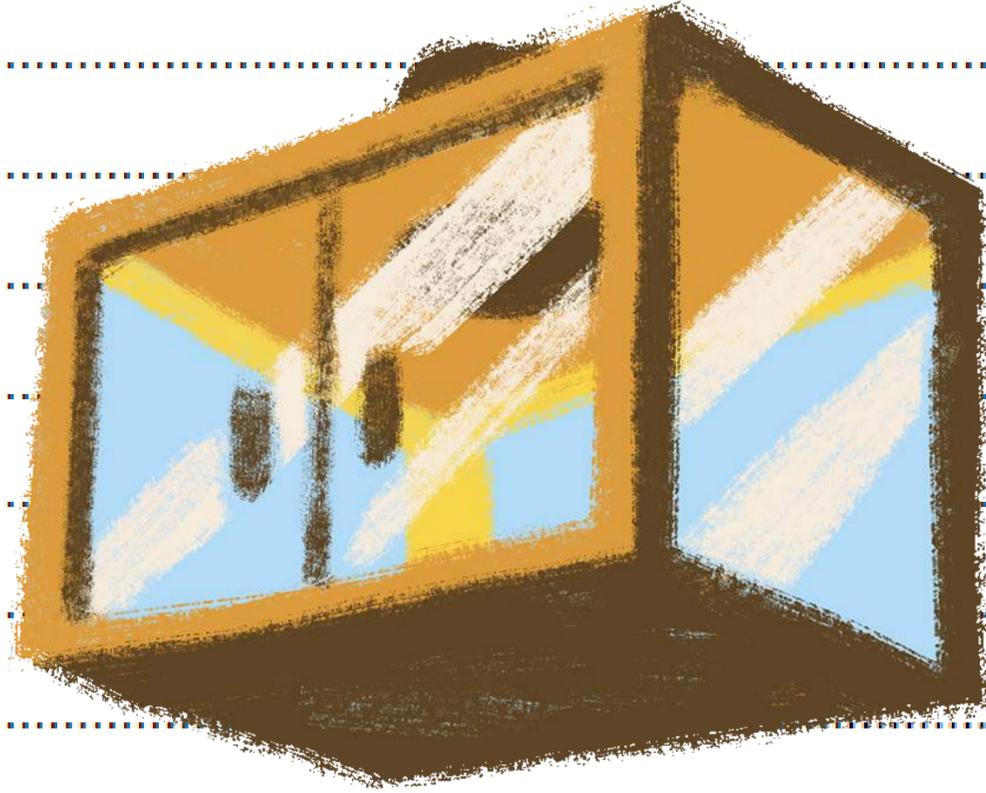
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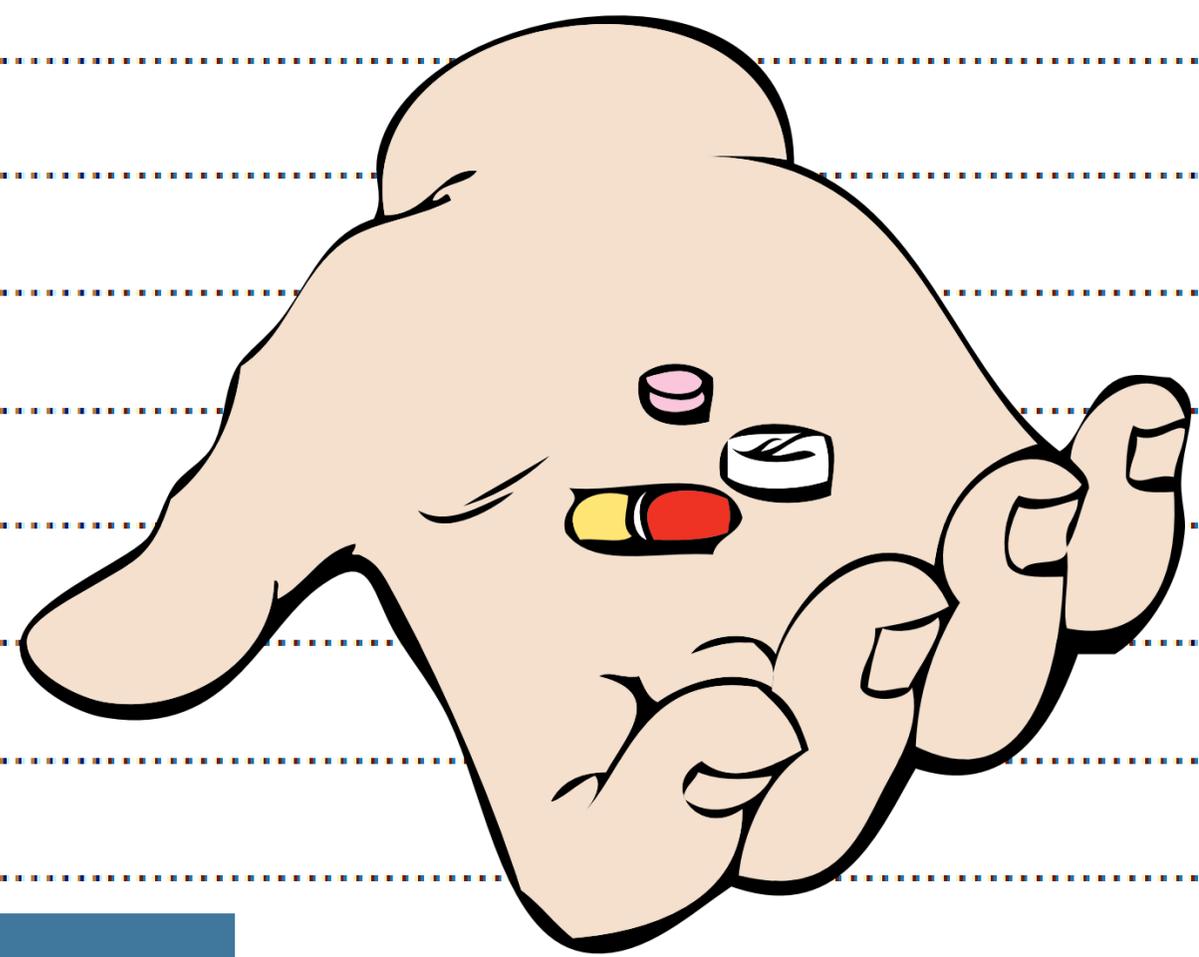
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Assumersi la responsabilità

COSA FARE

COSA NON FARE

Il nostro ruolo

le parole chiave



Consapevolezza



Comprensione



Disciplina