The Global Health Network

Sourcing, Preparing and Accounting for Investigational Products

UCT CLINICAL RESEARCH CENTRE

every step of the study

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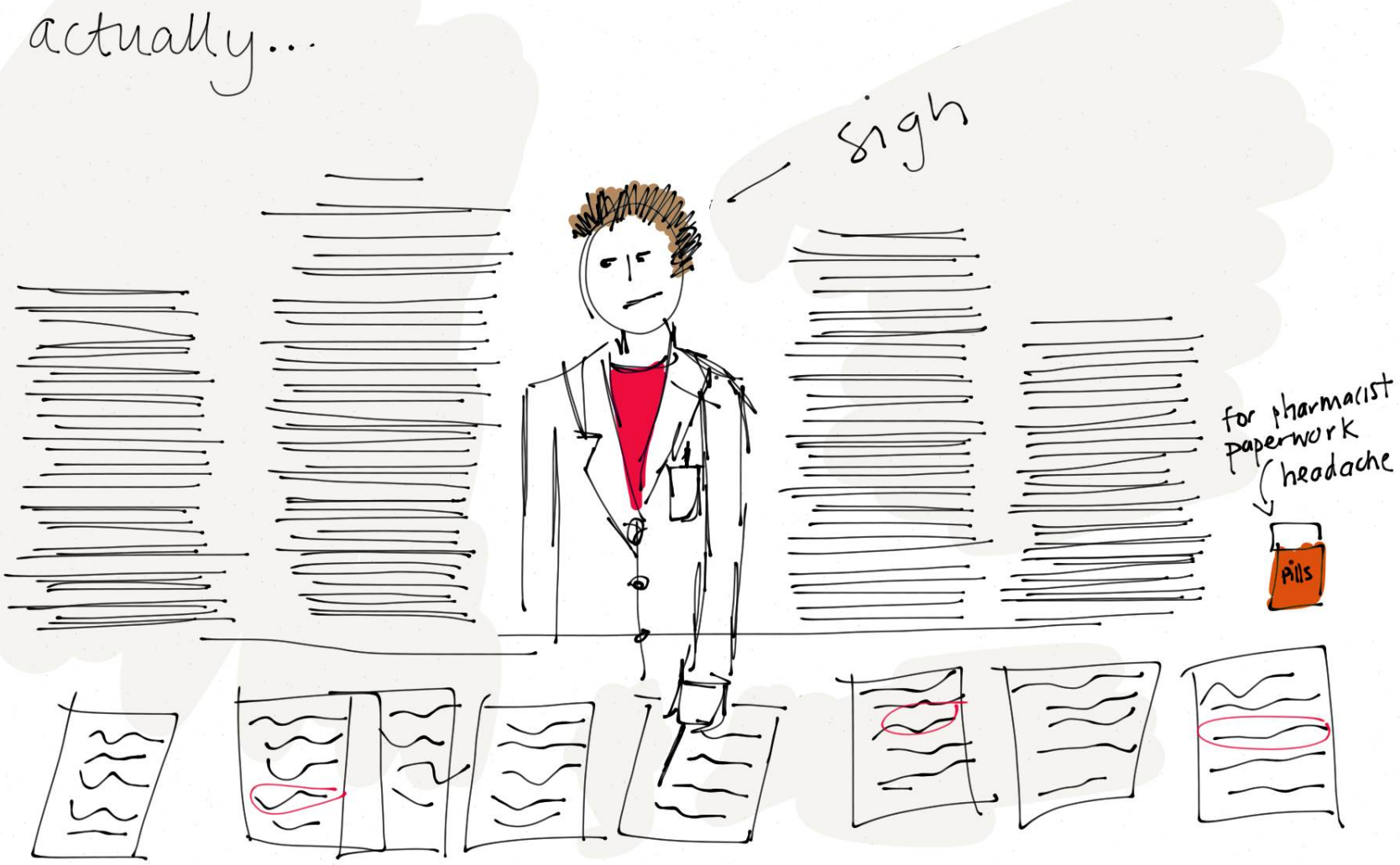
PILLS
...123, 124, 125...
... ? ... uuum..
128, no.... wait..
#?!@!


actually...
sigh
for pharmacist paperwork headache
pills

IMP/IP

IMP (Investigational Medicinal Product) / IP (Investigational Product)

1. Sourcing and Receipt
2. Storage
3. Dispensing/Blinding
4. Randomisation
5. Disposal/Destruction

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Sourcing and Receipt

Sponsor-driven Phase I:

- New IMP & Formulation
- Sponsor arranges manufacture
- Importing
- Dummy Dispensing

Investigator-led Phase III:

- Typically Locally-Marketed Product
- Pharmacist sources IMP
- Dummy Dispensing

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Source of Accountability:
Delivery waybills, Prescriptions, Invoices,
Receipt Accountability

Receipt Accountability

	University of Cape Town Clinical Research Centre	IMP receipt form

Protocol number/title:
Investigator (indicate PI, National, coordinating):

Each lot/batch should be documented on a separate sheet

Item	Details
Name of IP (if applicable)	
Dosage form	
Packaging form	
Manufacturer	
Lot/batch no.	
Expiry date	
Date of manufacture	
Date of receipt	
Received from	
Storage conditions	
Type of documentation received	

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Storage

- Certificate of Analysis (COA)
  → light, temperature, humidity
- Rigorous Control
  → E.g. fridges, air-con, probes, light protection
- Unique Storage Space
- Back-Up Plan

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Sources of Accountability:
Temperature Logs, Calibration Certificates, SOPs, COAs

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Dispensing

- Dispensing Licence
- Expiry Dates
- IP prep (e.g. reconstitution, infusion)
- Labelling requirements
  → e.g. Participant ID, Study/Protocol/Investigator ID, Quantity Dispensed, Mode of Delivery, Storage Condition, Exp./Lot/Batch #'s
- Blinding – implication for dispensing directly to patient
- Unblinding procedure

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Source of accountability:
MCC documentation, Pharmacy Manual (accountability, labels, patient dispensing logs)

Store Accountability

University of Cape Town Clinical Research Centre	Pharmacy/IMP store accountability form

Protocol number/title:	IMP name/formulation:
Investigator (indicate PI, National, coordinating):	Batch/lot number and expiry date:

DATE	IMP RECEIVED at Pharmacy/IMP Store					IMP removed from Pharmacy/IMP Store					Balance			Signature/date of pharmacist
	Transaction: • Shipment from supplier • Return from site / ward • Packing / labelling	Participant numbers	No. of [units]			Transaction: • Return to supplier • Supply to site / ward • For destruction	Participant numbers	No. of [units]			Packed		Unpacked	
			Packed		Unpacked			Packed		Unpacked				
			Used	Unused				Used	Unused		Used	Unused		

Comments:			
PI signature:		Date	

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Randomisation

- Treatment Allocation/Dispensing
- Generated by statistician/pharmacist (sponsor or site produced), stored in secure location e.g. pharmacy file
  → Randomisation schedule or Automated system e.g. IVRS
- Randomisation log

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Source of accountability:
Randomisation schedule and Randomisation logs

Randomisation Schedule Accountability

SOP Template IP05.F1 Randomisation and/or dose adjustment Page __ of __

THIS SOP FORM REMAINS THE PROPERTY OF THE CLINICAL RESEARCH CENTRE

	University of Cape Town Clinical Research Centre		**Acknowledgement of IP receipt**
Study number		**Sponsor**	University of Cape Town

Randomization list for Somerset Hospital

Enrolment number	Treatment allocation	Signature	Date
Screening01	Placebo		
Screening02	Active		
Screening03	Active		
Screening04	Placebo		
Screening05	Active		
Screening06	Placebo		
Screening07	Active		
Screening08	Placebo		

Randomisation Log Accountability

Randomization Log for: ACTIVE IMP

Sponsor code

RANDOMIZATION FORM

RANDOMISATION FOR SUBJECT: E-_____

Treatment to be assigned:

ACTIVE IMP (formulation de ils)

Step	Check	Details
IMP with "non-blinded" treatment label	☐	Batch n°_____ Study code-enrolment #
Apply the final "blinded" treatment label with the subject randomization number and complete all fields	☐	
Remove the original "non-blinded" treatment label and stick it here	☐	

Randomization by:	Randomization controlled by:
Name	Name

Randomization Log for: PLACEBO FOR IMP

Sponsor code

RANDOMIZATION FORM

RANDOMISATION FOR SUBJECT: E-_____

Treatment to be assigned:

PLACEBO FOR IMP (formula on details)

Step	Check	Details
IMP with "non-blinded" treatment label	☐	Batch n°_____ Study code-enrolment #
Apply the final "blinded" treatment label with the subject randomization number and complete all fields	☐	
Remove the original "non-blinded" treatment label and stick it here	☐	

Randomization by:	Randomization controlled by:
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Return/disposal

- At conclusion of study, final inventory and reconciliation
- Sponsor-driven: return to sponsor for disposal or site arranges disposal
- Arrange with waste disposal company

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Source of accountability:
Disposal/Destruction Log

Destruction Log Accountability

University of Cape Town Clinical Research Centre	IMP receipt for destruction form

Protocol number/title:
Investigator (indicate PI, National, coordinating):

This is to certify the delivery of the clinical trial pharmaceutical listed below to a drug disposal organisation.

IMP name/number	Formulation	Quantity			Batch/lot no	Expiry date
		Packed		Unpacked		
		Used	Unused			

Authorised by	Designation	Signature	Date
	Principal Investigator		
Delivered by	**Designation**	**Signature**	**Date**

SUMMARY

- Importance of pharmacy role: ***maintains accountability of IMP from start to finish, ensuring right dose given to right patient at the right time***
- Accountability is a continuous process from start of study until closure
- Inform/involve pharmacy at the outset
- Resources available on CRC website - http://www.crc.uct.ac.za/

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Services & Facilities

Over and above freely available advice, training and tools, the CRC is building capacity such that FHS clinical researchers may buy certain services rather than employ their own staff to take on these roles. UCT FHS is developing core facilities...

Read More

THE GLOBAL HEALTH NETWORK | SACRA

Quick Links

- Study design & protocol development
- UCT Sponsorship
- Ethics
- Regulatory & other approvals
- Project & quality management
- Data management, analysis & publication
- Investigational Products

The Faculty of Health Sciences (FHS) aims to support UCT FHS staff in their conduct of high quality clinical research (research involving people, their tissue, behaviour and/or data) from an initial idea to the final report. Focus areas include the governance, funding, design, operational conduct, analysis and reporting of clinical research projects initiated by UCT staff (particularly emerging researchers) and/or sponsored by UCT. However, all clinical researchers, whether from UCT or not, are able to make use of documents and information available on this website.

A team of experienced staff can, at no charge, guide and advise researchers in key aspects of conducting their clinical research projects, bringing in other experts where necessary. In addition, the CRC helps researchers identify qualified and experienced research team members and provides certain services and facilities for a fee.

Specifically, the CRC works with researchers to manage risk to their study participants and study staff, and also to the university. Thus, over and above the university's broader research integrity-related policies, and existing ethical review processes, the CRC has a mandatory process in place for researchers who are conducting projects where UCT has agreed to be the Sponsor. This includes adherence to certain standard operating processes. These, together with advice, training and tools, are also freely available for use in non-UCT sponsored research. All CRC outputs are intended to reflect relevant international, national and local regulations or guidelines.

Global Research Nurse competition

The Global Research Nurses' network is pleased to announce the second competition for nurses working in clinical research

Global Health Trials 2014 - Competition Results!

SAVE THE DATE!

The 2nd South Africa Global Health trials meeting will be held at UCT on the 19th September 2014. Details of the topics will be available shortly.

Feature your clinical research here!

We'd like to feature UCT clinical

Study design and protocol development
Sponsorship
Ethics
Regulatory and other approvals
Project and quality management
Data management, analysis & publication
Investigational products

Investigational products

Medicines

South African GCP has the following definition for an **Investigational Product** (which is synonymous with **Study Product**, and termed **Investigational Medicinal Product (IMP)** in Europe):

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Trials using Investigational Products must adhere to South African Good Clinical Practice (GCP) and Good Pharmacy Practice (GPP), both of which reference South African Good Manufacturing Practice (GMP).

If the Investigational Product is not pre-packaged by the Sponsor, and uses anything other than a simple dilution or reconstitution, please talk to the CRC for advice about whether you must adhere with the onerous full GMP requirements.

Whoever compounds and/or dispenses Investigational Product must be legally authorized to do. Currently this situation is unclear, however, it appears to be that, for clinical trials, a registered nurse is not allowed to dispense.

Devices

Toolkit

SOPs

Receiving IMP
Packaging and labeling IMP
Dispensing, dosing and return of IMP
Disposal of IMP

IMP receipt form
Pharmacy IMP store accountability form
Label requisition and printing form
IMP label
Packing of IMP form
Investigator accountability form
IMP return form
IMP receipt for destruction form

Factsheets

Destruction of IMP
Importing study drugs

Other useful documents

Questions?