COMMON GCP, MS IIT & CRM INSPECTION FINDINGS 2017

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Health Sciences Authority Singapore

OUTLINE

- General Overview
- GCP Inspections
- MS IIT Inspections
- CRM Inspections
- Case Studies

GCP, MS IIT and CRM Inspections 2009-2017

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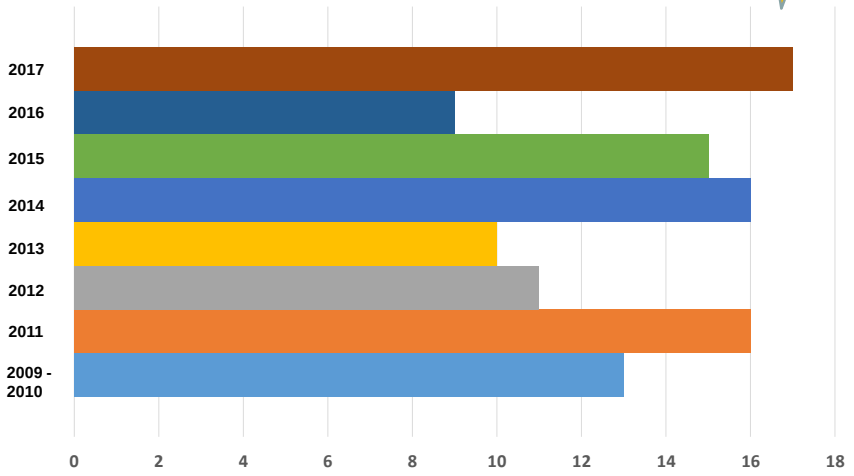
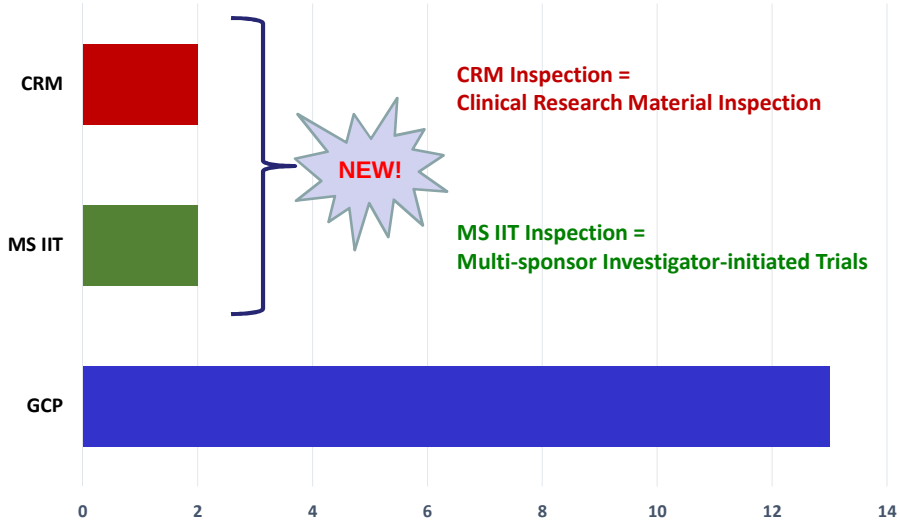


Types of Inspections in 2017



CRM Inspection =
Clinical Research Material Inspection

MS IIT Inspection =
Multi-sponsor Investigator-initiated Trials

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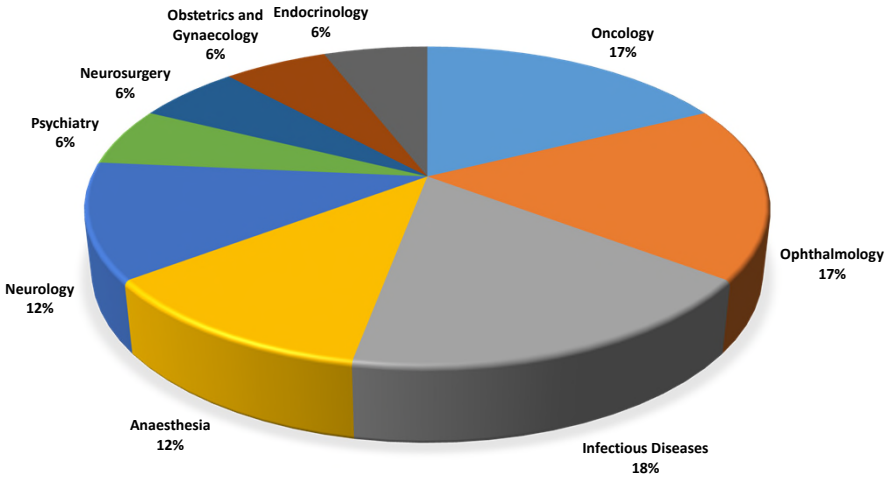
Distribution by Therapeutic Areas (N=17)



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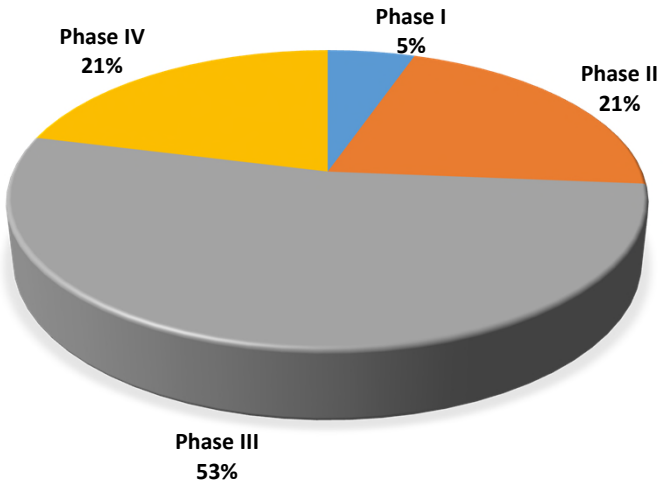
Distribution by Phases of Clinical Trials (N=19)



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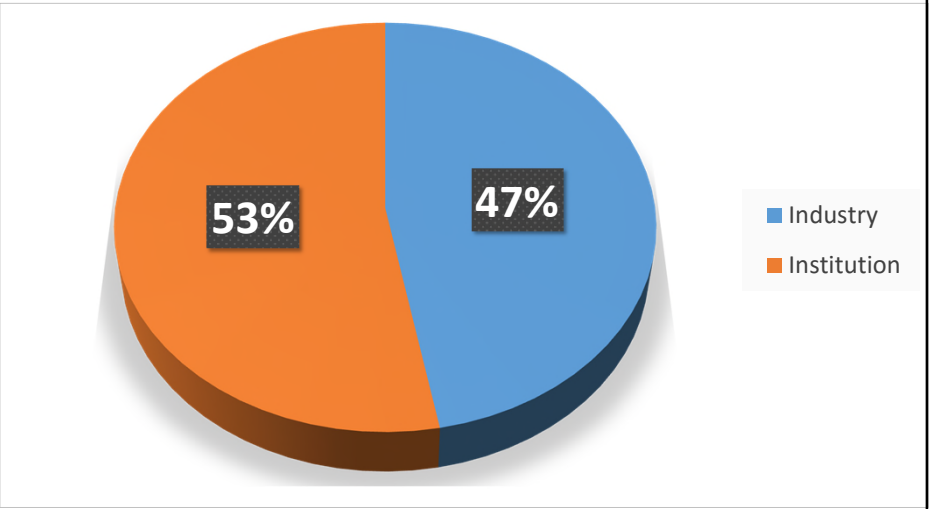
Distribution by Sponsors (N=17)



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Objectives of GCP Inspections

- To safeguard the Rights, Safety and Well-Being of trial subjects.
- To verify the Quality and Integrity of the clinical trial data submitted to the Regulatory Authority.
- To assess Compliance to protocol and applicable regulations, guidelines and standard operating procedures for clinical trials.

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Classification of GCP Inspection Findings

- **Critical:** Conditions, practices or processes that adversely affect the rights, safety or well being of the subjects and/or the quality and integrity of data.
- **Major**: Conditions, practices or processes that might adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data.

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Classification of GCP Inspection Findings

- **Other**: Conditions, practices or processes that would not be expected to adversely affect the rights, safety or well being of the subjects and/or the quality and integrity of data.

- **Comments**: The observations might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

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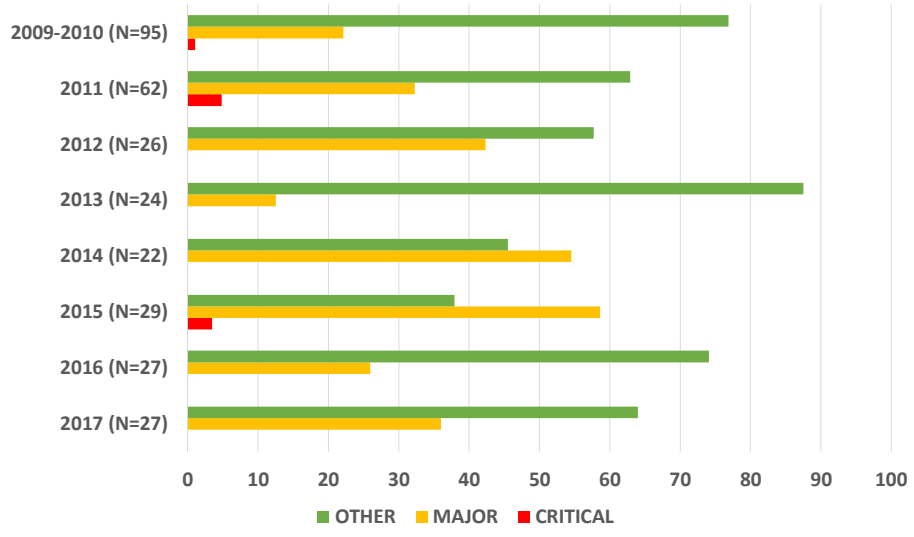
Classification of GCP Inspection Findings



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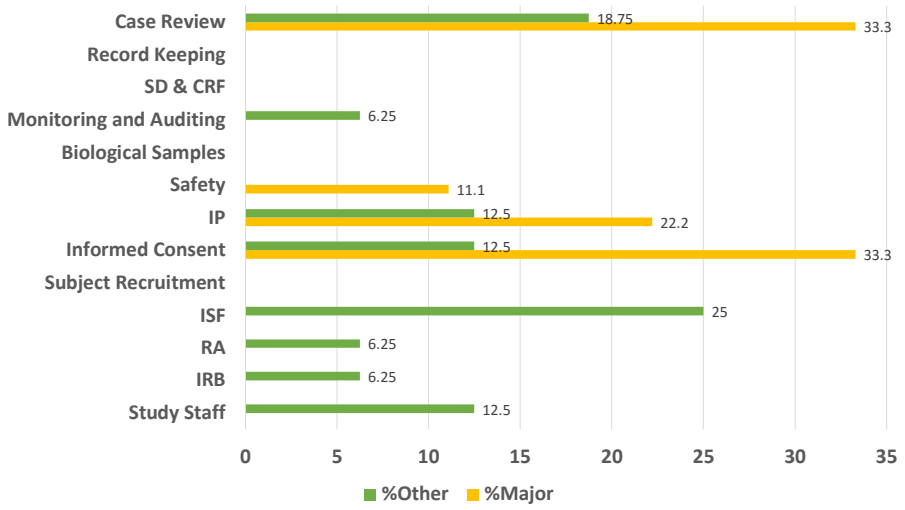
Distribution of GCP Inspection Findings in 2017



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Common GCP Inspection Findings
Informed Consent

- Informed consent obtained by Sub-investigator, who was not a locally registered medical doctor.
  - ► *Regulation 18(1) of Health Products (CT) Regulations*

REMINDER:

- Informed consent must be obtained by an investigator who is:
  - ❑ Locally registered doctor / dentist; and
  - ❑ Authorised by the Principal Investigator to obtain informed consent.

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Common GCP Inspection Findings
Informed Consent

- Monitor had acted as the impartial witness for the informed consent of a subject who was unable to read the informed consent.
  - ► *Sections 1.26 and 4.8.9 of ICH E6 (R2) GCP Guidelines*
  - ► *Regulation 18(4) of the Health Products (Clinical Trials) Regulations*

REMINDER:
❑ The impartial witness should be independent of the trial and not easily influenced by people involved in the trial.

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Common GCP Inspection Findings
Informed Consent in Adults Lacking Capacity

- The person who had provided substituted consent for the subject lacking capacity did not qualify as a legal representative
  - ► *Regulations 2(3) and 16(4) of the Health Products (Clinical Trials) Regulations*

INFORMED CONSENT IN ADULTS LACKING CAPACITY

Adult defined as ≥ 21 years, or < 21 years and is/was married

- Investigator and an independent doctor must certify that:
  (a) The adult lacks capacity to consent to being a subject in the trial; and
  (b) It is not likely that the adult will regain capacity within the window period.
- Consent from **Legal representative**

Is there a **donee** appointed by the adult subject before he/she lost capacity?

YES → **Donee must give consent.**

NO → Does the subject have a **deputy** appointed after he/she lost capacity?

YES → **Deputy must give consent.**

NO → Consent obtained from the following persons, in descending order of priority?
(a) spouse;
(b) adult child;
(c) parent or guardian;
(d) adult sibling;
(e) any other adult named by the adult (when the adult did not lack capacity) as someone to consult on the issue of the adult being a subject.

INFORMED CONSENT IN ADULTS LACKING CAPACITY

[A] Spouse of the adult;

[B] Adult child of the adult;

[C] Parent or guardian of the adult;

[D] Adult sibling of the adult; or

[E] Any other adult named by the adult (i.e. when the adult did not lack capacity) as someone to consult on the issue of the adult being a subject.

[a] The order of priority applies in the absence of actual notice of any contrary indication given by the subject or prospective subject (when the subject or prospective subject did not lack capacity);

[b] A person cannot be a legal representative of the subject or prospective subject if the person is also a donee or deputy, and there is an express provision in the lasting power of attorney or appointment by the court that the donee or deputy is not authorised to give consent to the subject or prospective subject being a subject;

[c] The person referred to in [B], [C], [D] or [E]:

- may be a legal representative only if all persons having a higher priority compared to that person are not available or cannot be a legal representative by reason of sub-paragraph (a) or (b); and
- cannot be a legal representative if any person having an equal or a higher priority compared to that person (other than a person who cannot be a legal representative by reason of sub-paragraph (a) or (b)) has objected to being a subject.

ICF Documentation Template for Adults Lacking Capacity

Developed by TTSH CRIO and Singapore Infectious Disease Clinical Research Network

INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

CLINICAL TRIAL TITLE

A. SUBJECT DETAILS

Name	
NRIC / BC / FIN	
Date of Birth	

PASTE SUBJECT STICKER HERE

B. WRITTEN CERTIFICATION FOR LACK OF CAPACITY

I examined the adult patient and certify that this patient lacks capacity within the meaning of Section 4 of the Mental Capacity Act. On the basis of this examination I certify in writing that:

INVESTIGATOR		**INDEPENDENT DOCTOR**	
The investigator must be a qualified practitioner and authorised to obtain informed consent.		*The independent doctor must be a qualified practitioner and not part of the study team.*	
I certify that: ☐ This patient lacks capacity to consent to being a subject. It is not likely that the patient will regain capacity within the window period: _____ *(Specify the window period as required by the protocol)* Remarks (if any): _____		I certify that: ☐ This patient lacks capacity to consent to being a subject. It is not likely that the patient will regain capacity within the window period: _____ *(Specify the window period as required by the protocol)* Remarks (if any): _____	
Name		Name	
Designation		Designation	
Department		Department	
MCR No.		MCR No.	
Signature		Signature	
Date:	Time:	Date:	Time:

INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

C. INFORMED CONSENT IN ADULTS LACKING CAPACITY

The legal representative[1] giving consent for the adult lacking capacity must act in the best interest of the subject. Please refer to the explanatory note (refer to Page 4) on who can be a legal representative.

[1]Explanatory note on who can be a legal representative

A legal representative for adults lacking capacity, as defined in the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations is:

(i) the donee or deputy appointed pursuant to or under the Mental Capacity Act in relation to the giving or refusing of consent on behalf of the adult to be a subject; or

(ii) where there is no donee or deputy referred to in (i), any of the following persons in descending order of priority:*
- *[A] a spouse of the adult;*
- *[B] an adult child of the adult;*
- *[C] a parent or guardian of the adult;*
- *[D] an adult sibling of the adult; or*
- *[E] any other adult named by the adult (i.e. when the adult did not lack capacity) as someone to consult on the issue of the adult being a subject.*

**For the purpose of (ii), all of the following applies:*

(a) The order of priority applies in the absence of any contrary indication given by the subject or the prospective subject (when the subject / prospective subject did not lack capacity);

(b) A person referred to in (ii) cannot be a legal representative if the person is also a donee or deputy, and there is an express provision in the lasting power of attorney or appointment by the court that the donee or deputy is not authorised to give consent to the adult being a subject;

(c) A person referred to in [B], [C], [D] or [E] –
- *May be a legal representative only if all persons having a higher priority compared to that person are not available or cannot be a legal representative by reason of (a) or (b); and*
- *Cannot be a legal representative if any person having an equal or higher priority compared to that person (other than a person who cannot be a legal representative by reason by (a) or (b)) has objected to the adult being a subject.*

ICF Documentation Template for Adults Lacking Capacity

Developed by TTSH CRIO and Singapore Infectious Disease Clinical Research Network

INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

Steps	Assessment	Guidance Notes
Step 1: Does this patient have a **donee**?	☐ Yes. • *Check the patient's certified LPA Form.* • *Is there an express provision in the certified LPA Form that the donee is not authorized to given consent to the adult being a subject?* ☐ *Yes (if yes, donee may not give consent; proceed to the next step)* ☐ *No (if no, the donee may give consent)* o *Name of donee:_____* ☐ No. Proceed to next step.	Retain copy of the patient's certified LPA form.
Step 2: Does this patient have a **deputy**?	☐ Yes. • Check the patient's certified Court Order Letter. • Is there an express provision in the certified Court Order Letter that the deputy is not authorized to give consent to the adult being a subject? ☐ Yes (if yes, deputy may not give consent; proceed to the next step) ☐ No (if no, the deputy may give consent) • Name of deputy:_____ ☐ No. Proceed to next step.	Retain copy of the patient's certified Court Order Letter.
Step 3: Does this patient have a **spouse**?	☐ Yes. A spouse may give consent unless otherwise indicated under the Health Products (Clinical Trials) Regulations or Medicines (Clinical Trials) Regulations[1]. Name of subject's spouse:_____ ☐ No. Proceed to next step.	Document relationship to the patient in the patient's medical records.
Step 4 Does this patient have an **adult child**?	☐ Yes. An adult child may give consent unless otherwise indicated under the Health Products (Clinical Trials) Regulations or Medicines (Clinical Trials) Regulations[1] Name of subject's adult child:_____ ☐ No. Proceed to next step.	Document relationship to the patient in the patient's medical records. There is no order of priority if the patient has more than one adult child.

INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

Steps	Assessment	Guidance Notes
Step 5 Does this patient have a **parent or a guardian**?	☐ Yes. The parent / guardian may give consent unless otherwise indicated under the Health Products (Clinical Trials) Regulations or Medicines (Clinical Trials) Regulations[1]. Name of subject's parent/ guardian: _____ ☐ No. Proceed to next step.	Document relationship to the patient in the patient's medical records.
Step 6 Does this patient have an **adult sibling**?	☐ Yes. The adult sibling may give consent unless otherwise indicated under the Health Products (Clinical Trials) Regulations or Medicines (Clinical Trials) Regulations[1]. Name of subject's adult sibling: _____ ☐ No. Proceed to next step.	Document relationship to the patient in the patient's medical records. There is no order of priority if the patient has more than one adult sibling.
Step 7 Does this patient have any other adult named (when the patient did not lack capacity) as someone to consult for clinical trial participation?	☐ Yes. He/she may give consent unless otherwise indicated under the Health Products (Clinical Trials) Regulations or Medicines (Clinical Trials) Regulations[1]. Name of named adult by subject: _____ ☐ No. The subject should not be enrolled.	Ensure there is adequate documentation to justify the decision to approach this adult.

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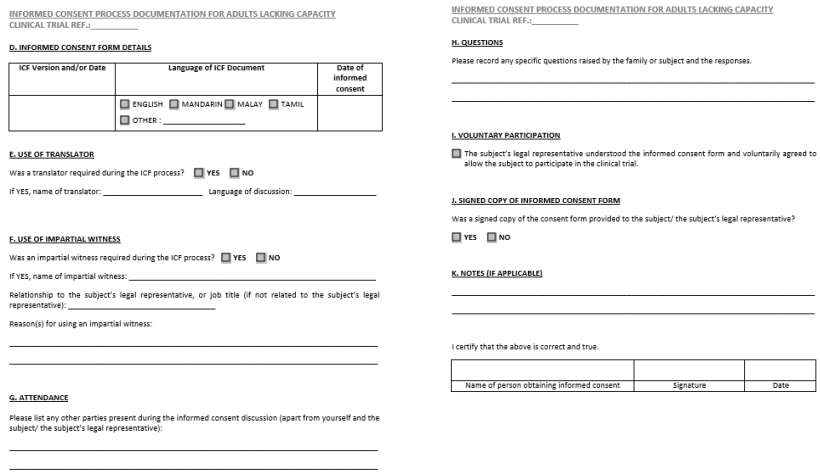
ICF Documentation Template for Adults Lacking Capacity

Developed by TTSH CRIO and Singapore Infectious Disease Clinical Research Network



INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

D. INFORMED CONSENT FORM DETAILS

ICF Version and/or Date	Language of ICF Document	Date of informed consent
	☐ ENGLISH ☐ MANDARIN ☐ MALAY ☐ TAMIL ☐ OTHER : _____	

E. USE OF TRANSLATOR

Was a translator required during the ICF process? ☐ YES ☐ NO

If YES, name of translator: _____ Language of discussion: _____

F. USE OF IMPARTIAL WITNESS

Was an impartial witness required during the ICF process? ☐ YES ☐ NO

If YES, name of impartial witness: _____

Relationship to the subject's legal representative, or job title (if not related to the subject's legal representative): _____

Reason(s) for using an impartial witness:

_____

_____

G. ATTENDANCE

Please list any other parties present during the informed consent discussion (apart from yourself and the subject/ the subject's legal representative):

_____

_____

INFORMED CONSENT PROCESS DOCUMENTATION FOR ADULTS LACKING CAPACITY
CLINICAL TRIAL REF.:_____

H. QUESTIONS

Please record any specific questions raised by the family or subject and the responses.

_____

_____

I. VOLUNTARY PARTICIPATION

☐ The subject's legal representative understood the informed consent form and voluntarily agreed to allow the subject to participate in the clinical trial.

J. SIGNED COPY OF INFORMED CONSENT FORM

Was a signed copy of the consent form provided to the subject/ the subject's legal representative?

☐ YES ☐ NO

K. NOTES (IF APPLICABLE)

_____

_____

I certify that the above is correct and true.

Name of person obtaining informed consent	Signature	Date

Common GCP Inspection Findings

Informed Consent in Adults Lacking Capacity

- Consent for continued participation was not obtained from the adult after the adult re-gained the capacity to give consent.
  - ► *Regulation 16(9) of the Health Products (Clinical Trials) Regulations*

REMINDER:

❑ Consent for continued participation must be obtained from the subject once the subject regains the capacity to give consent.

Common GCP Inspection Findings

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Investigational Product (IP)

For blinded CT involving IP repackaging

- Lack of traceability to product.
- No evidence of line clearance during repackaging process.
- Lack of written procedures for handling of IP.
  - ► *Sections 2.13, 4.9.0, 5.14.3 of ICH E6 (R2) GCP guidelines*

Common GCP Inspection Findings

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Investigational Product (IP)

For blinded CT involving IP repackaging

- The correspondences relating to IP management were not clearly delineated between the masked and unmasked teams, thereby potentially compromising the treatment blind.
  - ► *Section 2.13 of ICH E6 (R2) GCP guidelines*
- The unmasked CRC had dispensed the IP to the subjects prior to study-specific training on IP management.
  - ► *Section 4.2.4 of ICH E6 (R2) GCP guidelines*

Maintaining Study Blind

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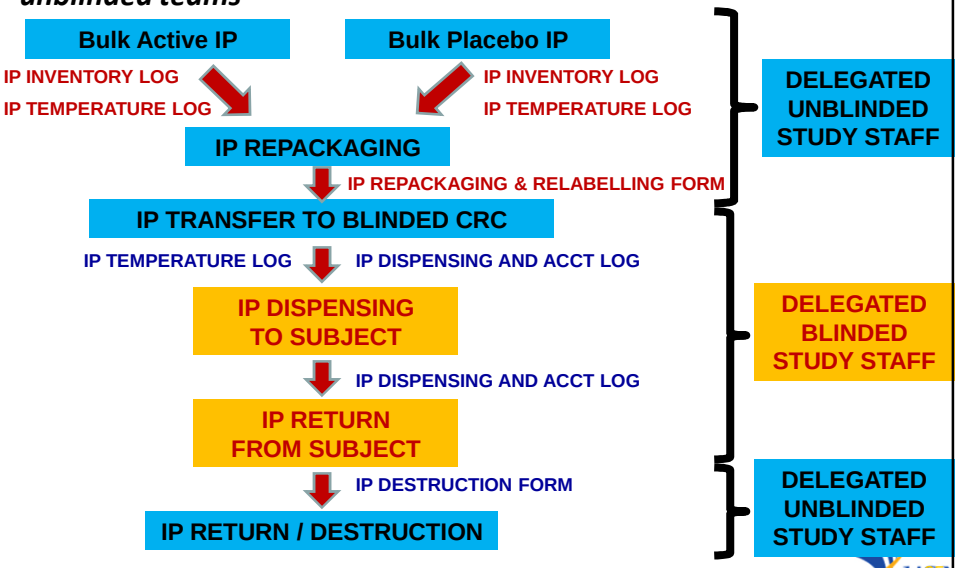
Clear delineation in roles and responsibilities of blinded and unblinded teams



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GMP Principles for IP Re-packaging

- ❑ *SOPs*
- ❑ *Delegated and trained study staff*
- ❑ *Line clearance*
- ❑ *In-process control checks (e.g. witness)*
- ❑ *Label re-conciliation*
- ❑ *Documentation*

➢ *PICS Annex 13 : Sections 23-25*

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Principles of IP/AP Labelling

(a) to ensure protection of the subject and traceability;

(b) to enable identification of the product and the clinical trial;

(c) to facilitate proper use and storage of the product;

(d) to ensure the reliability and robustness of data generated in the clinical trial.

- *Paragraph 1(1) of Second Schedule of Health Products (CT) Regulations*
- *Paragraph 1(1) of Third Schedule of Health Products (Therapeutic Products as Clinical Research Materials) Regulations*

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Multi-sponsor Investigator-initiated Trials (MS IIT) Inspections

- **Scope**
  - Clinical trials regulated under the Health Products (Clinical Trials) Regulations or the Medicines (Clinical Trials) Regulations.

- **Objectives for MS IIT Inspections (Systems):**
  - To safeguard the rights, safety and well-being of trial subjects.
  - To verify the quality and integrity of the clinical trial data submitted to the Regulatory Authorities
  - To assess compliance to protocol, applicable regulations, guidelines and standard operating procedures for clinical trials.
  - To assess whether a system is suitably designed, controlled, maintained and documented to fulfill the objectives for which it has been set up.
  - To identify areas for quality improvement.

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Multi-sponsor Investigator-initiated Trials (MS IIT) Inspections

- **MS IIT Inspection Criteria**
  i. Protocol
  ii. Applicable clinical trials and clinical research materials regulations
  iii. ICH E6 (R2) Good Clinical Practice Guidelines [ICH E6 (R2) GCP]
  iv. Applicable Sponsor / Contract Research Organization (CRO) / Site Standard Operating Procedures for clinical trials

- **Inspectee**
  - Lead sponsor
  - Other sponsor

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Common MS IIT Inspection Findings
Lead Sponsor Responsibilities - MAJOR

- Substantial amendments to informed consent form were not submitted to HSA.
  - ► *Regulation 10(2) of the Health Products (Clinical Trials) Regulations*
- Laboratory kits had been imported into Singapore without CRM Notification.
  - ► *Regulation 4 of Health Products (Medical Device) Regulations*

REMINDER:
❑ Lead sponsor must be aware of lead sponsor responsibilities in addition to sponsor responsibilities.

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Additional Legal Duties for Lead Sponsors and Other Sponsors for MS IITs

Lead Sponsor

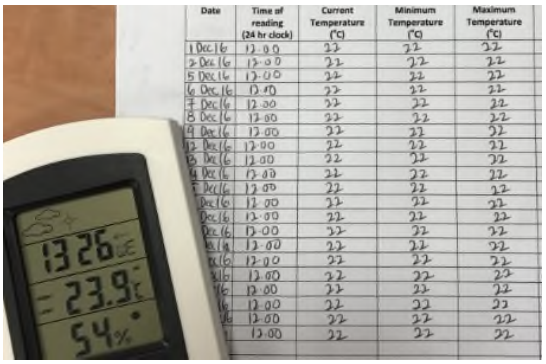
1. Regulatory submissions and notifications to HSA (e.g. CTC/CTA/CTN applications, amendments, serious breaches, trial status reports, final trial reports, etc)
2. Ongoing safety evaluation of study drug(s) administered to subject
3. Prompt notification to all participating site investigators/institutions of findings that could adversely affect subject safety or impact conduct of trial
4. Notification of unexpected serious adverse drug reactions, and serious breaches of GCP/protocol, to HSA

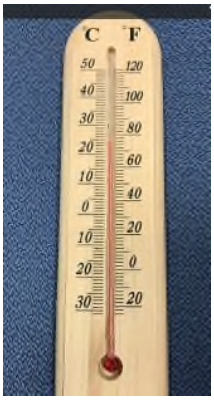
Other Sponsor(s)

1. Report immediately to lead sponsor any SAE at participating site, or any finding that could adversely affect subject safety or impact conduct of trial
2. Provide all relevant information to lead sponsor that is necessary for the lead sponsor to perform trial-related regulatory submissions and notifications to HSA

Common MS IIT Inspection Findings
Investigational Product - Critical

- IP Storage Temperature Logs were inaccurate.
  - *Sections 2.10 and 4.9.0 of ICH E6 (R2) GCP Guidelines*





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Clinical Research Material (CRM) Inspections

- **Scope**
  - Clinical trials regulated under the Health Products (Clinical Trials) Regulations or the Medicines (Clinical Trials) Regulations.

- **Objectives**
  - CRM is supplied for clinical research approved by the IRB and HSA;
  - Records of manufacture, receipt, supply and disposal (or export or putting to other use) are maintained;
  - CRM is properly labelled.

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Clinical Research Material (CRM) Inspections

- **CRM Inspection Criteria**
  i. Protocol
  ii. CRM Regulations i.e.
    - Health Products (Therapeutic Products as Clinical Research Materials) Regulations - for Therapeutic Products used as CRM.; or
    - Medicines (Medicinal Products as Clinical Research Materials) Regulations - for Medicinal Products used as CRM.
  iii. ICH E6 (R2) Good Clinical Practice Guidelines [ICH E6 (R2) GCP]
  iv. Standard Operating Procedures (SOPs)

- **Inspectee**
  - Local sponsor
  - Local Depot
  - Local Trial Sites

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Common CRM Inspection Findings

- Discrepancies in CRM inventory between IVRS report and physical stock at site.
  - ► *Regulation 16(1) of Health Products (TP as CRM) Regulations*
- *Discrepancies in records for CRM receipt and supply*
  - ► *Regulation 16(1) of Health Products (TP as CRM) Regulations*

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Common CRM Inspection Findings

- Discrepancies in CRM Storage
  - Temperature loggers were not re-calibrated;
  - Reports from temperature loggers were not reviewed regularly;
  - Min-max thermometer was not re-set after temperature excursion;
  - Temperature excursions were not reported to the sponsor.
  - Temperature logs for another CT had been filed without blinding the trial information of the latter trial.

  - ➢ *Sections 4.6.4 and 4.9.0 of the ICH E6 (R2) Good Clinical Practice Guidelines*

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CASE STUDY

- Protocol Title: A phase 3, randomised, double-blind, placebo-controlled clinical trial comparing the safety and efficacy of Bipisartan and placebo in hypertension.
- Principal Investigator: Dr Lauren Wong
- Clinical Research Coordinator: Ms Gina Ong

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SCENARIO 1

- Mr Lee Hock Seng (80 yrs, moderate Alzheimer's disease) was enrolled into this clinical trial.
- He was accompanied by:
  - His wife is 70 yrs, mentally competent, wheel-chair bound; and
  - His son, Mr Andy Lee.

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ICF for Scenario 1

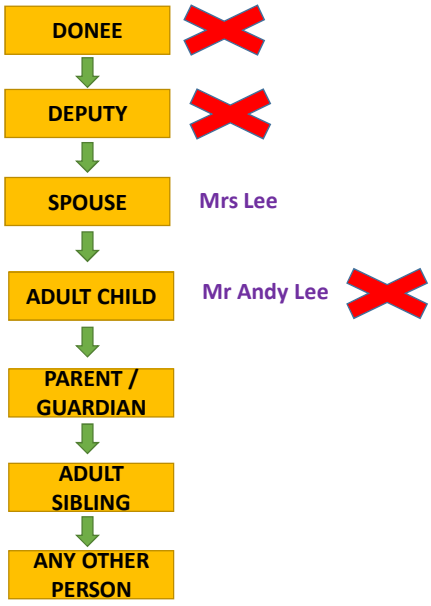
Lee Hock Seng		
Name of Subject	Signature	Date
Andy Lee		1/9/2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

ICF for Scenario 1 - ANSWER

Lee Hock Seng		
Name of Subject	Signature	Date
Andy Lee	A	1/9/2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

- Not acceptable for Mr Andy Lee (son) to act as the legal representative.
- Mr Lee Hock Seng's wife should have acted as the legal representative.

ALGORITHM FOR CONSENT IN ADULTS LACKING CAPACITY



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SCENARIO 2

- Mr Lee Hock Seng (80 yrs, moderate Alzheimer's disease, widower) was enrolled into this clinical trial.
- Before Mr Lee Hock Seng lost capacity, he had nominated in writing that his younger brother, Mr Lee Hock Boon, should take charge of his affairs in the event that he lost capacity.
- Mr Lee Hock Seng was accompanied to the trial site by his son, Mr Andy Lee.

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ICF for Scenario 2

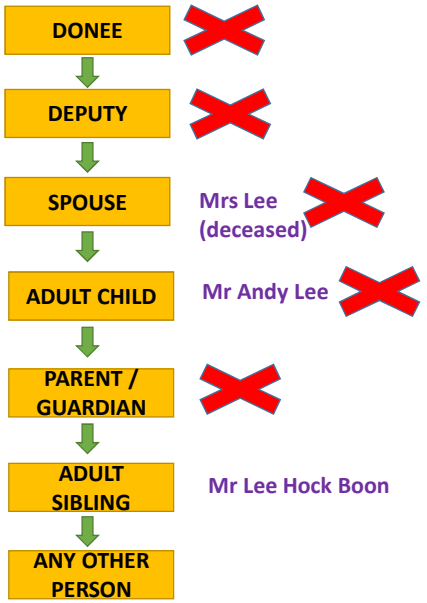
Lee Hock Seng		
Name of Subject	Signature	Date
Andy Lee		1/9/2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

ICF for Scenario 2 - ANSWER

Lee Hock Seng		
Name of Subject	Signature	Date
Andy Lee	A	1/9/2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

- Not acceptable for Mr Andy Lee (son) to act as the legal representative.
- Mr Lee Hock Seng's brother should have acted as the legal representative.

ALGORITHM FOR CONSENT IN ADULTS LACKING CAPACITY



SCENARIO 3

- Mr Lee Hock Seng (80 yrs, moderate Alzheimer's disease) was enrolled into this clinical trial.
- He was accompanied by his wife (Mrs Lee) and his younger brother (Mr Lee Hock Boon).
- Before Mr Lee Hock Seng lost capacity, he had nominated in writing that his younger brother, Mr Lee Hock Boon, to be his donee in the event that he lost capacity.

SCENARIO 3

OFFICE OF THE PUBLIC GUARDIAN

LASTING POWER OF ATTORNEY FORM 1 (2014)

Hotline: 1800-226-6222
Website: www.publicguardian.gov.sg

PART 3 — **POWERS GRANTED TO THE DONEE**

(The term "donee" includes all donees (if more than one is appointed for that particular power) and a replacement donee.)

PART 3A *Personal Welfare*

My donee shall have the authority to make decisions in all matters relating to my personal welfare, where I (the donor) no longer have the mental capacity to make such decisions:

☑ Yes ☐ No (please tick one box only)

If 'Yes' then:

a. My donee's authority shall be subject to the terms of this lasting power of attorney and the provisions of the Act.

b. My donee's authority shall extend to giving or refusing consent to the carrying out or continuation of treatment, including the conduct of a clinical trial, by a person providing health care for me:

☐ Yes ☑ No (please tick one box only)

c. Where there is more than 1 donee, they shall act (please tick one box only):

☐ Jointly

☐ Jointly and severally

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ICF for Scenario 3

Lee Hock Seng		
Name of Subject	Signature	Date
Lee Hock Boon	Lee	1 Sep 2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

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ICF for Scenario 3 - ANSWER

Lee Hock Seng		
Name of Subject	Signature	Date
Lee Hock Boon	Lee	1 Sep 2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date

- Not acceptable for Mr Lee Hock Boon (donee) to act as the legal representative, as he was not given the power to decide on trial participation.

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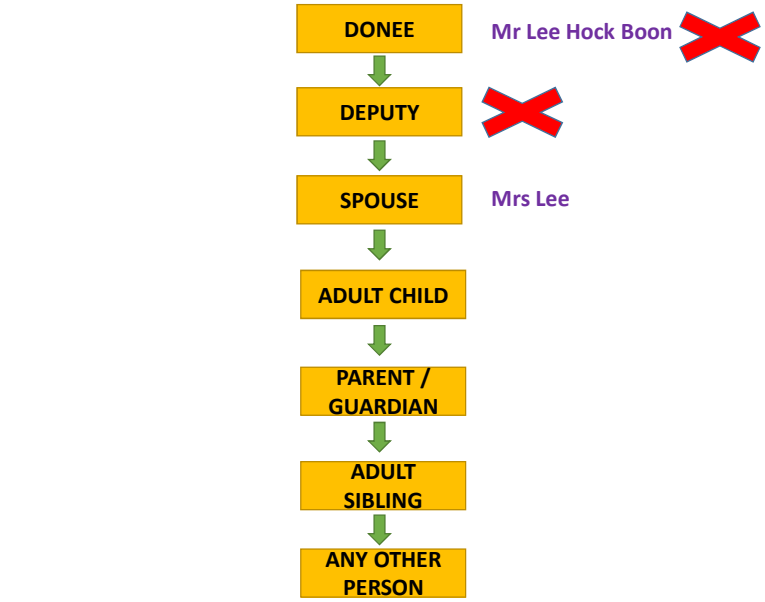
ALGORITHM FOR CONSENT IN ADULTS LACKING CAPACITY



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SCENARIO 4

- Mr Lee Hock Seng (80 yrs, moderate Alzheimer's disease, widower) was enrolled into this clinical trial.
- His son, Mr Andy Lee, looks after him.
- Mr Lee Hock Seng was accompanied by his brother, Mr Lee Hock Boon, to the trial site for the first study visit.

ICF for Scenario 4

Lee Hock Seng		
Name of Subject	Signature	Date
Lee Hock Boon	Lee	1 Sep 2016
Name of Legal Representative	Signature	Date
Name of Impartial Witness	Signature	Date
Dr Lauren Wong		1/9/2016
Name of Investigator	Signature	Date