

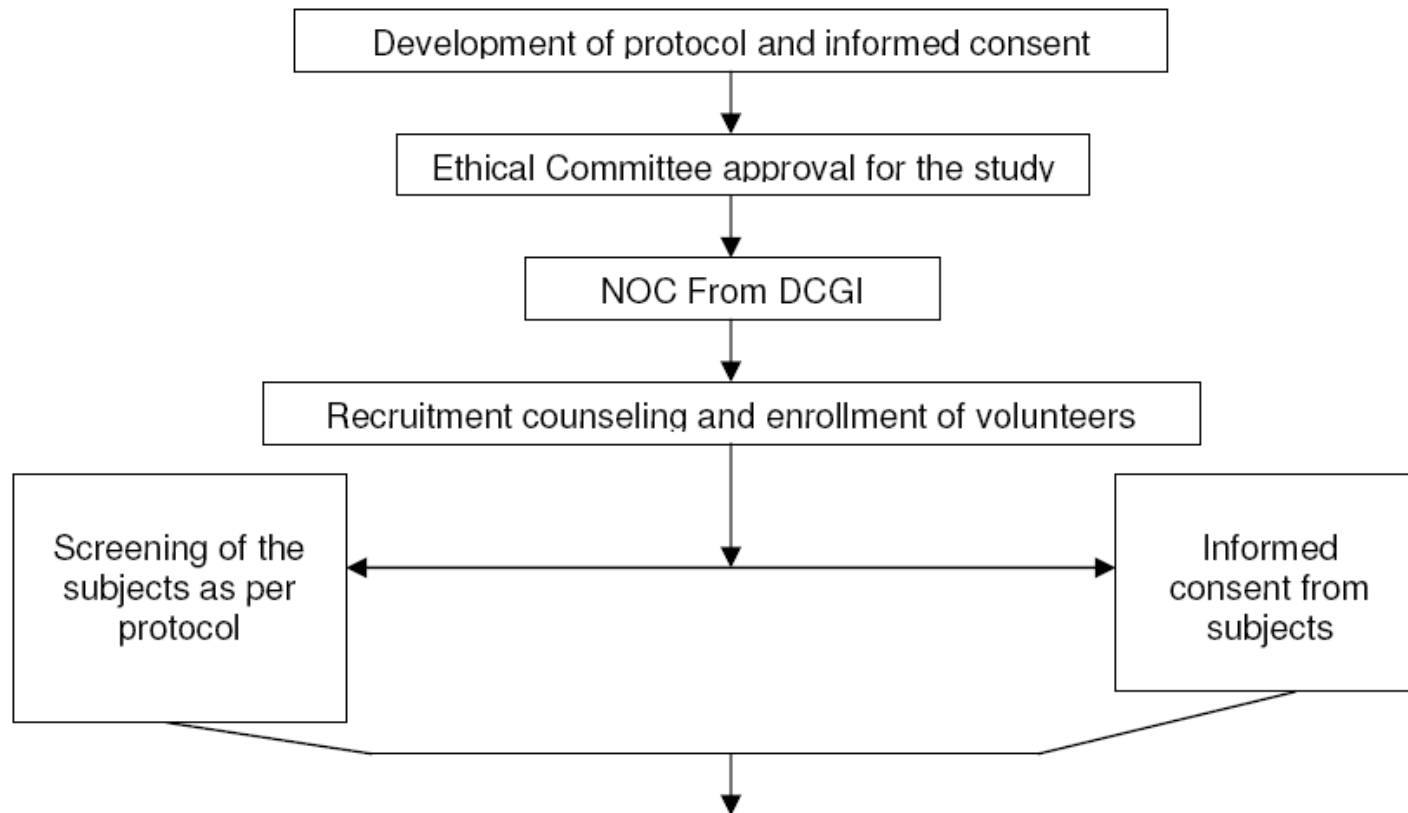


BA/BE STUDIES

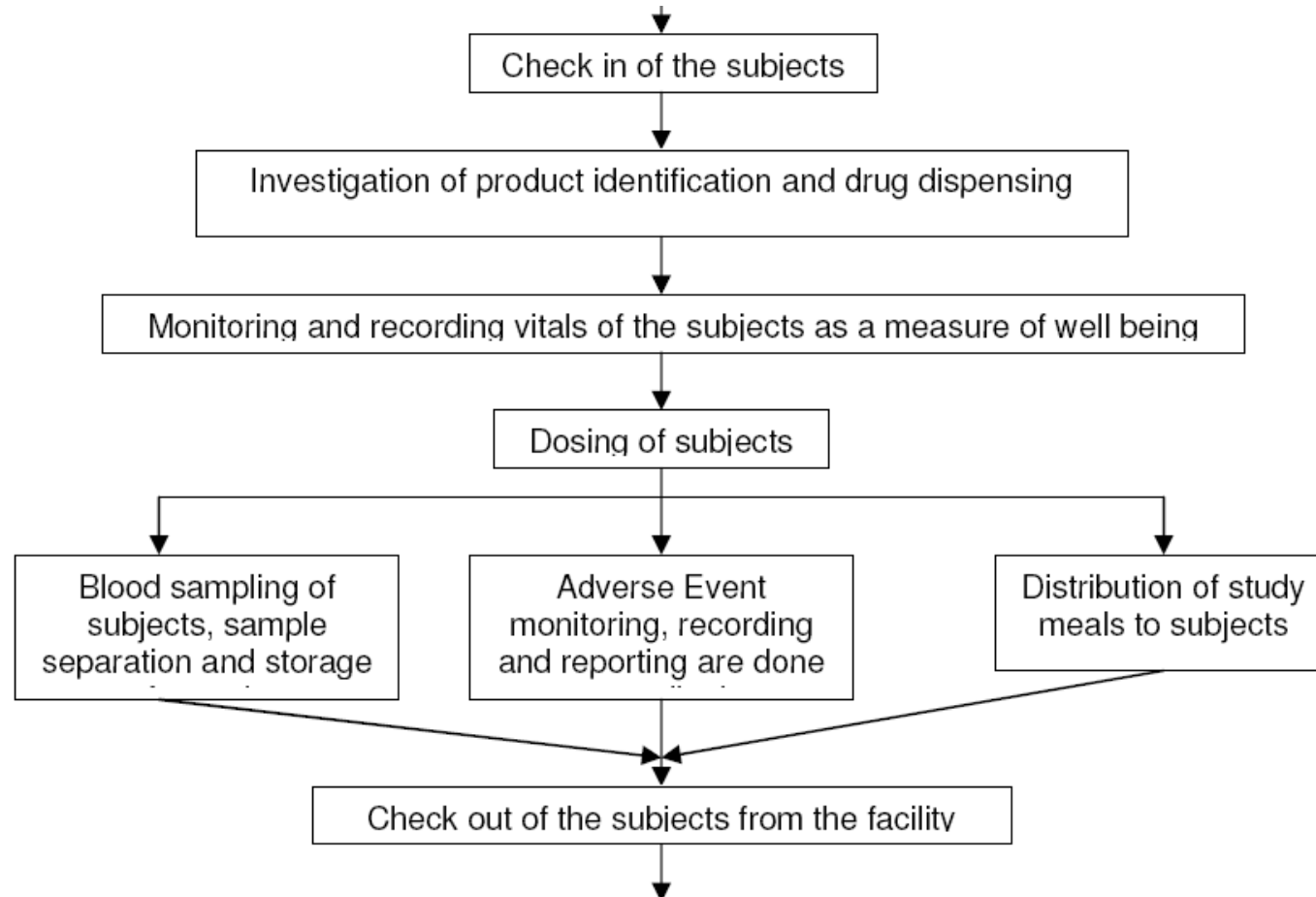
TYPES OF BA/BE STUDIES

- Food effects studies
- Single and Multiple dose
- Steady state studies
- Immediate release and modified release products
- Pharmacodynamic studies
- Interaction studies
- Drugs with narrow therapeutic range
- Special populations
- Various routes of delivery

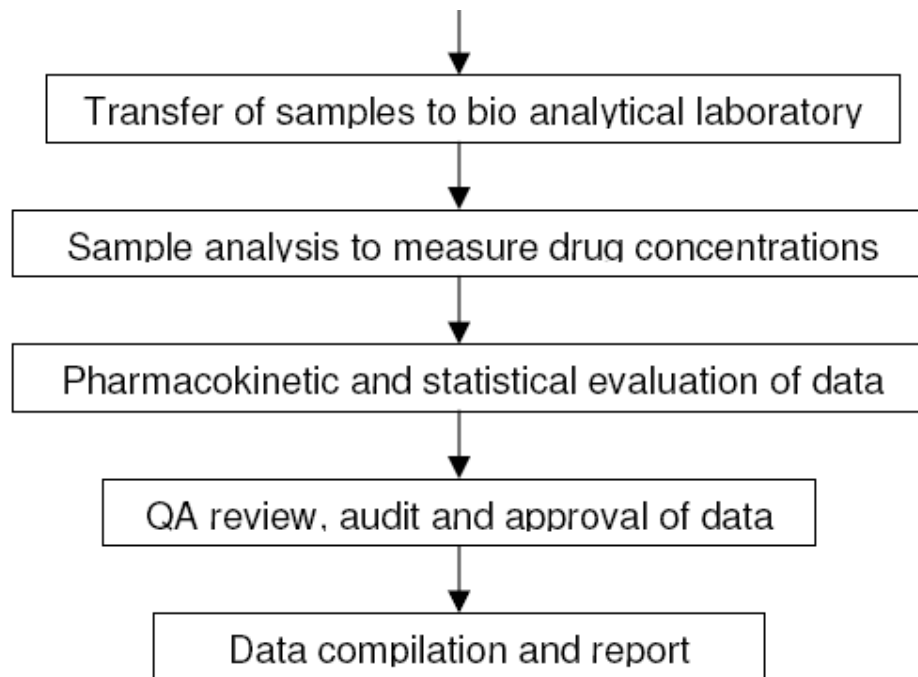
PROCESS FLOW OF BA/BE STUDIES



PROCESS FLOW OF BA BE STUDIES



PROCESS FLOW OF BA BE STUDIES



CLINICAL FACILITY

RESEARCH TEAM

- Principal Investigator
 - Communicate with Ethical Committee
 - Ensure compliance with SOP and ICH-GCP
 - Ensure safety and welfare of the participant
 - Record and report all the relevant safety information
- Project Manager
 - Define and clarify project objectives
 - project timelines and tasks
 - Co-ordination with sponsor's
 - Prepare and conduct successful team meetings

RESEARCH TEAM

- Quality Assurance
 - Promote quality throughout the entire organization
 - Conducts internal audits and data quality control reviews
 - Impart training on GCP and SOPs
- Clinical Research Coordinator / Pharmacist
 - Receipt and accountability of investigational product
 - Supervise distribution of study meals
 - Ensure conformance to GCP / GLP



RESEARCH TEAM

- Clinical Investigator / Physician
 - Screening of volunteer's
 - Conduct BA/BE studies
- Staff Nurse, Lab Technician
 - Vitals Monitoring , Blood draws
 - Sample separations
- Custodian
 - Check in & Check out of Subjects
- Protocol and Report writers
 - Preparation of protocol and reports
- Volunteer Development Officer
 - Develop and maintain volunteer data base



CLINICAL PHARMACOLOGY UNIT (CPU)

- 30 beded air-conditioned, housing facility.
- Fully Equipped ICU.



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INTENSIVE CARE UNIT

- Fully Equipped with equipments like Defibrillator, Cardiac monitor etc.
- Emergency medicines & ICU drugs.



CRITICAL CARE SUPPORT

- Consent to provide prompt care incase of emergency
- ICU & CCU
- Ambulance service
- Less than 3 Km
- Multi specialty hospital

CENTRAL LABORATORY SERVICES

- From NABL/CAP Accredited labs
- Screening of Volunteer
- Safety Sample Analysis after study
- Demographic data, Medical and Medication histories, General Physical Examination and systemic examination, ECG, Chest X-ray, Hematology, Biochemistry, Serology and Urine analysis

VOLUNTEER COUNSELING

- Having Database of both male and female volunteer
- Valid age proof (18 to 45 yrs)
- Height & weight measurements (according to LIC chart)
- General Counseling
- HIV Counseling
- Avoid Smoking / Alcohol
- Tobacco products before 2 days & during study periods
- Avoid Medication for 14 days before
- Avoid Grape Fruit products before 2 days during study periods

INFORMED CONSENT PROCEDURE

- Distribution of ICD
- Verbal Speech
- Clarification of Doubts
- Written Informed Consent
- Impartial Witness
- Photo copy of ICD is given

SCREENING AREA

- General Consent from Volunteer's
- Medical History
- Physical Check up
- Diagnostic Test
- ECG, Chest X-Ray
- General Informed Consent
 - In a Language known to the volunteer



RECREATION AREA

- Flat Screen Television
- Carom board
- Chess
- Newspaper & Magazines

Pharmacy

Access controlled
Receipt
Storage
Dispensing &
Retention of investigational products.



BLOOD DRAW AREA

- Cannula Insertion
- Pre-dose Samples
- Post dose Samples
- Cannula Removal
- Direct Venepuncture



DOCUMENTATION AND ARCHIVAL

- Protocol & Report Writing.
- Clinical research coordinator
- Pharmacist
- Access controlled archival



BIOANALYTICAL FACILITY

STATE OF THE ART EQUIPMENTS

- ICP-MS
- AAS
- LC MS/MS – API 3000
- LC MS/MS – Agilent
- GC-MS
- GC-MS/MS
- HPLCs
- RT-PCR, PCR
- ELISA
- FTIR
- HPTLC
- GC-Headspace-FID
- GC-ECD,NPD
- Microwave reaction system
- Deep freezers
- Stability chamber

LIST OF BIOANALYTICAL METHODS

S. No.	Analyte	LLOQ	Unit	Matrix	Instruments
1	Amlodipine	0.5	ng/ml	Plasma	LC/MS/MS
2	Betamethasone	10	ng/ml	Plasma	LC/MS/MS
3	Cinnarizine	5	ng/ml	Plasma	LC/MS/MS
4	Curcumin	10	ng/ml	Plasma	LC/MS/MS
5	Diclofenac sodium	20	ng/ml	Plasma	LC/MS/MS
6	Domperidone	10	ng/ml	Plasma	LC/MS/MS
7	Flunarizine	10	ng/ml	Plasma	LC/MS/MS
8	Formoterol	10	ng/ml	Plasma	LC/MS/MS
9	Gatifloxacin	200	ng/ml	Plasma	LC/MS/MS
10	Ibuprofen	500	ng/ml	Plasma	LC/MS/MS
11	Metoprolol	10	ng/ml	Plasma	LC/MS/MS
12	Ofloxacin	200	ng/ml	Plasma	LC/MS/MS
13	Omeprazole	10	ng/ml	Plasma	LC/MS/MS
14	Pantoprazole	10	ng/ml	Plasma	LC/MS/MS
15	Phenobarbitone	250	ng/ml	Plasma	LC/MS/MS
16	Phenytoin	50	ng/ml	Plasma	LC/MS/MS
17	Piracetam	10	ng/ml	Plasma	LC/MS/MS
18	Propranolol	10	ng/ml	Plasma	LC/MS/MS
19	Rabeprazole	10	ng/ml	Plasma	LC/MS/MS
20	Vanoxerine	1	ng/ml	Plasma	LC/MS/MS
21	Salbutamol	2.5	ng/ml	Plasma	LC/MS/MS
22	Ganciclovir	10	ng/ml	Plasma	LC/MS/MS
23	Acyclovir	10	ng/ml	Plasma	LC/MS/MS
24	Trimethoprim	10	ng/ml	Plasma	LC/MS/MS
25	Silver	5	ng/ml	Plasma	ICP/MS
26	Silver	5	ng/gm	Tissue	ICP/MS
27	Artemether + Lumefantrine	20.0 & 250.0	ng/ml	Plasma	LC/MS/MS
28	Itraconazole	5	ng/ml	Plasma	LC/MS/MS
29	Carbamazepine	10	ng/ml	Plasma	LC/MS/MS
30	Levonorgestrel	0.25	ng/ml	Plasma	LC/MS/MS

Conti....

LIST OF BIOANALYTICAL METHODS

31	Rabeprazole	20	ng/ml	Plasma	LC/MS/MS
32	Cefixime+Dicloxacillin	200.0 & 500.0	ng/ml	Plasma	LC/MS/MS
33	Aceclofenac+Thiocolchicoside	411.72 & 1.79	ng/ml	Plasma	LC/MS/MS
34	Metformin	171.12	ng/ml	Plasma	LC/MS/MS
35	Oxcarbazepine and MHD (metabolite)	24.84 & 25.74	ng/ml	Plasma	LC/MS/MS
36	Ibuprofen + Paracetamol	403.31 & 212.84	ng/ml	Plasma	LC/MS/MS
37	Clopidogreal	0.141	ng/ml	Plasma	LC/MS/MS
38	Fluconazole	23.3	ng/ml	Plasma	LC/MS/MS
39	Cefixime + Ofloxacin	201.1 & 205.2	ng/ml	Plasma	LC/MS/MS
40	Theophylline	533.9	ng/ml	Plasma	LC/MS/MS
41	Bisoprolol	10	ng/ml	Plasma	LC/MS/MS
42	Atenolol	10.08 to 1557.54	ng/ml	Plasma	LC/MS/MS
43	Ambroxol	5.03	ng/ml	Plasma	LC/MS/MS
44	Losartan	5.71	ng/ml	Plasma	LC/MS/MS
Method in Progress					
45	Ondansetron			Plasma	LC/MS/MS
46	Azithromycin			Plasma	LC/MS/MS
47	Meloxicam			Plasma	LC/MS/MS
48	Progesterone			Plasma	LC/MS/MS
49	Metformin+Glimepiride			Plasma	LC/MS/MS
50	Lornoxicam+ Thiocolchicoside			Plasma	LC/MS/MS
51	Cefpodoxime + Dicloxacillin			Plasma	LC/MS/MS
52	Domperidone			Plasma	LC/MS/MS
53	Thicolchicoside			Plasma	LC/MS/MS
54	Metformin+Glimepiride+Pioglitazone			Plasma	LC/MS/MS
55	Pioglitazone			Plasma	LC/MS/MS
56	Glimepiride			Plasma	LC/MS/MS
57	Telmisartan			Plasma	LC/MS/MS

INFORMATION TECHNOLOGY

- Data storage and safety
 - Secure server
 - Firewall
 - Live Backups
 - Documentation management tool
 - Gigabit backbone
 - Compliant software





THANK YOU!

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