Case Report Form

Design and Format

Module 10 Topic 5.1

Definition

A **printed, optical, or electronic** document designed to record all of the **protocol required** information to be reported to the sponsor on each trial subject

GCP (consolidated Guideline) Section 1.11

CRF

- The forms used to record the **patient's data** obtained during the clinical study are collectively called as CRF

- CRFs are
  - Designed by the sponsor
  - Completed by the Investigators
  - Reviewed By the Monitor
  - Entered by the Data Management team
  - Analyzed by the Biostatistician

Instructions for CRF Designing

- Use inputs from the study team
- Request minimal free text responses
- Record dates to help trace source data
- There should be one CRF per subject
- Any parameter that will not be analyzed should not be included

CRF Responsibilities

Project Manager	Leads, manages, works with statistician, provides input on design, reviews
Investigator	Assures correct entering of CRFs
Monitor	Checks for accuracy and consistency
Data Manager	Reviews and edits
Statistician	Gives inputs, ensure CRF and database tally

Role of Investigators

- Assure all patients data is collected as per the protocol
- Record data in CRF as per the sponsor's requirements
- Assure consistency within the CRF
- Assure consistency between the CRF and SD
- Assure corrections are made (if required) as per monitor's remarks
- Sign the CRFs
- Retain Patient's SD and CRFs and assure that the monitor can access them during all the site visits

Role of Monitors

- Review CRFs to check for
  - Legibility and accuracy of the data
  - Consistency with the SD
  - Timely and accurate Adverse Event reporting
  - Study Drug Accountability
  - Protocol Deviations

Accurate Documentation

- Provides basis for safety and efficacy evaluation of the drug
- Documents protocol adherence and protection of human subjects
- Validates data integrity and analysis

The size, **Design, Content and Complexity** of the CRF depends upon the **stage and design** of the study

Contents of the CRF

- Must be protocol driven
- Must contain sections on
  - Study Number, Center Code, Patient Number
  - Name, signature of Investigator
  - Version, Date, Page numbers
  - Emergency Numbers
  - Instructions for filling the CRF
  - Study Flow Chart
  - Inclusion /Non-inclusion criteria
  - Demography of Patients
  - Medical History of Patients
  - Concomitant Medications/ Previous therapy
  - Current Illness (Signs and Symptoms/ Diagnosis)

Contents of the CRF (contd)

- Must contain sections on (contd)
  - Study Medication dosing details
  - General Examination
  - Laboratory Examination
  - Special Examination
  - Adverse Event Reporting
  - Serious Adverse Event Reporting
  - Compliance Check
  - Efficacy Parameters
  - Safety Parameters
  - Global Evaluation of Efficacy and Tolerability
  - End of Study Information


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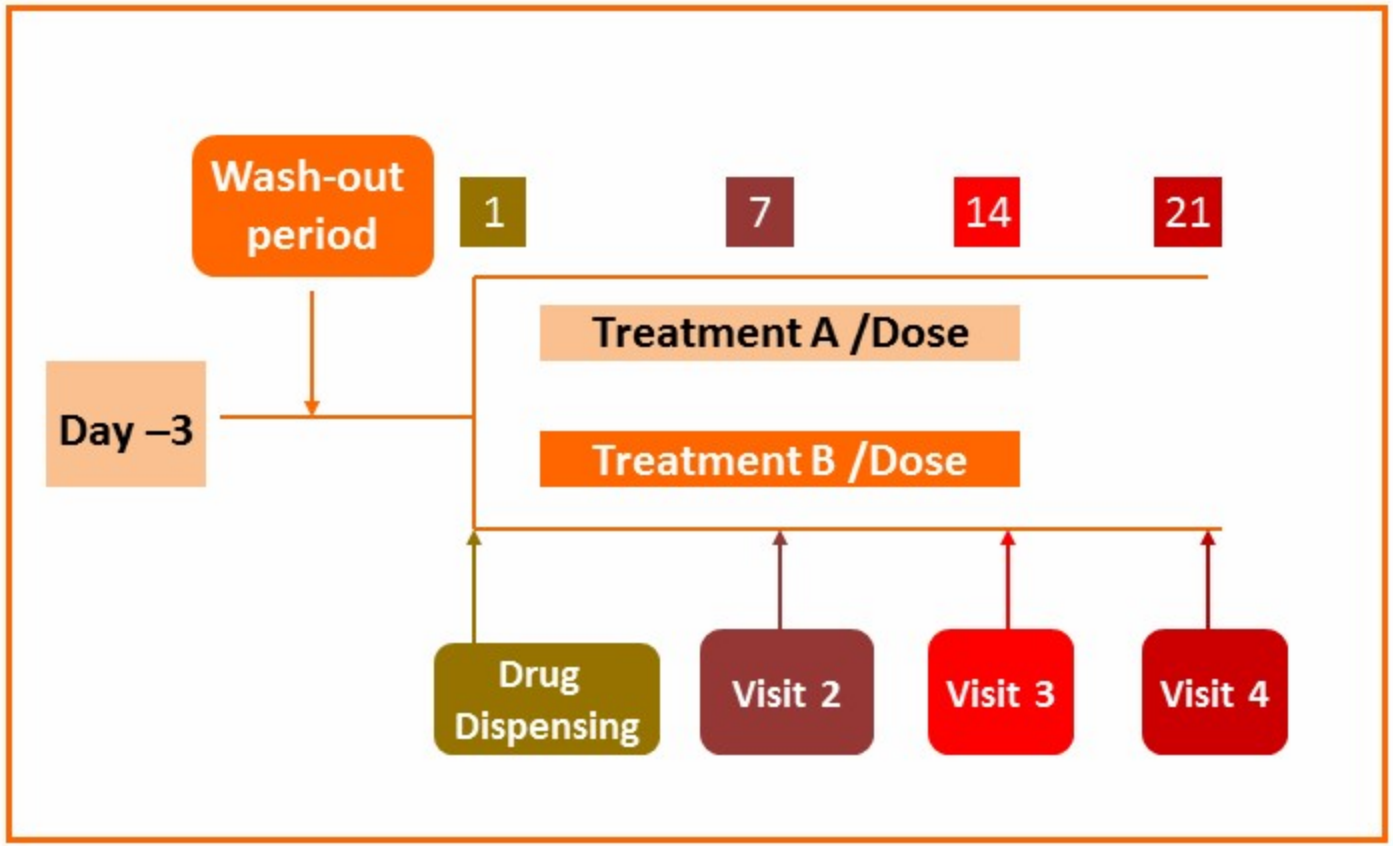
Instructions for Filling the CRF

- Enter Patient Number in CRF
- Ensure Patient Number in the CRF corresponds to the study medication packing
- Use only standard abbreviations
- For correction of any entries, strike out the incorrect entry with one line and enter correct entry alongside, initial and date it
- Enter data in black ball-point pen only

Study Flow Chart



Schedule of Observations

Parameter	Day – 3	Day 1	Day 7	Day 14	Day 21
Informed Consent	✓	-	-	-	-
Inclusion/ Exclusion	✓	Review	-	-	-
Lab Investigations	✓	-	-	-	✓
Compliance Check	-	-	✓	✓	✓
General Examination	✓	✓	✓	✓	✓

Inclusion Criteria

Please Check all statements and tick (✓) the appropriate box

- Morning stiffeness in and around joints lasting 1 hour

  Y ☐ N ☐

If the answer is "No" to any of the above, please do not enroll the patient

Exclusion Criteria

Please Check all statements and tick (✓) the appropriate box

- Pregnant/ Lactating woman and woman of child bearing potential not following adequate contraceptive measures

  Y ☐ N ☐

If the answer is "YES" to any of the above, please do not enroll the patient

Demography of Patients

Patient's Initials	
Age (in years)	
Sex	M☐ F☐
Weight (in Kg)	
Height (in cm)	

Concomitant Illness and Medications

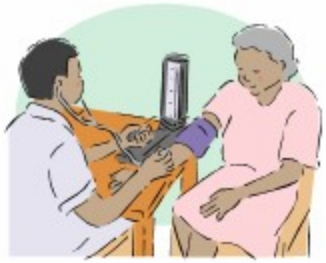
Condition	Name of The Drug (Generic)	Dosage Strength/ Frequency	Started on	Remarks
Hypertension	Atenolol	50mg OD	Date	

STUDY MEDICATION DOSING DETAILS

- Treatment A/B
- Dose: ____mg
- Frequency: OD/BID

General Examination

- VITAL SIGNS
  - Body Temperature
  - Pulse Rate
  - Blood Pressure



Laboratory Examination

- Complete Blood Count: **Hb, WBC, RBC, ESR, Platelets etc.**
- Enzymes: **Alkaline phosphatase, SGPT, SGOT etc.**
- Blood Sugar: **Fasting, PP, HbA1C**
- Urine Analysis
- ECG findings
- Other Investigations

Normal Lab values must be given either in the CRF or separately

Special Examination

- Depends on the type of the study
  - For Pain, pain VAS score is analysed
  - For Inflammation, swelling, redness, local temperature, pain are analysed
  - For RA, HAQ score is determined
  - For hypertension, DBP, SBP average of 3-6 readings are taken into consideration

Adverse Event Reporting

- Did the patient experience any of the following?

Event	**Yes / No**	**Severity** Mild/Moderate /Severe	**Treatment** If given Drug, Dose	**Outcome** Continued/ resolved
Nausea				
Abdominal Discomfort				

Serious Adverse Event Reporting

Efficacy Parameters

- By Investigator
- By Patients

Open Vs Closed Design

Open Ended Questions

- Give Details of Patient's Medical History

Close Ended Questions

- Does patient have any clinically significant medical history?

  Y ☐ N ☐

- If yes, fill the following details

Body System	Normal	Abnormal	Comments What? Since when?
CVS			
Respiratory System			
CNS			
Eyes/ Ear			

The success of the clinical trial depends not only upon the design of the study protocol but also upon the methods employed to ensure that clinical data are of high quality and in suitable format for statistical analysis

Future?

- WEB- BASED TRIALS / E- Trials/ EDC