Client Name: CIPLA Protocol #:CP/02/16 Review of:CRF Screen

Reviewed by: Resolved by name & Title:

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| Project Manager | Programmer | Monitor | RajeshreePowle(Senior CDM) |
| Clinical Data Manager | Statistician | Clinician |
| Client (Name and Title):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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| **Item Reviewed**  (If applicable, specify the versionof the document reviewed) | **Meets Specification?** | | **Reviewed by (Initial & Date)** | **Resolution Notes** | | **Resolved by (Initial & Date)** |
| Yes  or  No | Patient no. 001 |  | Resolved? Yes or No | Provide resolution notes |  |
| ALL FORM |  | All form name needs to be reflected in capital letter | SP | Yes | We have changed all the form names to capital letters.  Resolved | Rajitha G 06/10/2017 |
| STUDY CODE | No | This form is not required. Only Patient No. and Centre No. is required to be displayed on each form header. |  | Yes | We Removed all the forms named “study code “and added the protocol header which displays in header of all the forms.(Instead of site name site code is displaying.We will change it to site name after configuring the edit checks)  Resolved | Rajitha G 06/10/2017 |
| AUDIO CONSENT FORM | No | This information is missing. |  | Yes | We added Audio consent form and panel  Resolved | Rajitha G 06/10/2017 |
| Screening Visit |  | Screening visit is included in Inform Consent. Please create new form for screening visit | SP | Yes | Screening Visit Form is separated from Informed Consent form.  Resolved | Rajitha G 06/10/2017 |
| INFORMED CONSENT |  | Time format is nog given to Time Field  |\_\_|\_\_|: |\_\_|\_\_| | SP | Yes | Changed the textbox to multi input textbox  Resolved | Rajitha G 06/10/2017 |
| DEMOGRAPHY – (DM) | No | Age: I was able to enter the value in this field and when I hit the enter key the DM form got skipped and PREVIOUS AND CONCOMITANT MEDICATIONS appeared for entry. This field should not be enterable field. |  | Yes | Edit Check need to be configure for this field to auto populate the field.  OK  Resolved | Rajitha G 06/10/2017 |
| DEMOGRAPHY – (DM) |  | DEMOGRAPHY – (DM)- Not allowing to update Partial date (UN-UNK-1980) | SP | Yes | Partial Dates entry will not allow by default. If you specify the particular fields in the study where the partial dates can be enterable. We need to configure for that fields alone.  Please create this field as Partial Date field | Rajitha G 06/10/2017 |
| DEMOGRAPHY – (DM) |  | Weight field is allowing to update 5 continue number however it should be 5.2 that is 123.45 (3 digit prior to decimal and 2 digit after) | SP | Yes | Field length is increased to 6 characters and changed to decimal data type.  More than one decimal (….) is allowing to update | Rajitha G 06/10/2017 |
| DEMOGRAPHY – (DM) | No | Date you have to select from the calendar only. Can us not directly able to enter the date in the date field to save the DE time. |  | Yes | By default it will select from the calender but if user need to have data entry means development team has to make changes. If you want to change as manual entry for all the fields please let us know.  Only for Partial date we need Manual entry or UN-UNK for Date-month in calendar | Rajitha G 06/10/2017 |
| All forms | No | Skip logics are missing. |  | Yes | Skip logics will be configured after the study design completed.  Resolved | Rajitha G 06/10/2017 |
| MEDICAL AND SURGICAL HISTORY | No | Body system code should be drop down menu. |  | Yes | Changed the Body System code field textbox to dropdown menu.  HEM is missing from drop down  Resolved | Rajitha G 06/10/2017  Updated |
| MEDICAL AND SURGICAL HISTORY |  | If “Yes”, please provide details: should be differentiated from main Question (By entering space between Question and comment) | SP | Yes | Separated as two points  This field do not require text box. Its only a comment  Resolved | Rajitha G 06/10/2017  Updated |
| MEDICAL AND SURGICAL HISTORY | No | Please fill in the details note Previous **and concomitant Medications is in bold.** On the form it is not in bold. |  | Yes | Right now in the system, we do not have a feature of having half text as normal and half text as bold in full sentence. Development change need to be done.  Ok  Resolved | Rajitha G 06/10/2017 |
| ECG | No | Time format is not showing as 12:45 after entering the data. |  | Yes | Changed from textbox to multi input textbox.  **Time** format needs to be added  Resolved | Rajitha G 06/10/2017  Need Clarification |
| ADVERSE EVENT MONITORING |  | In comment bold the Yes as below:  If **Yes**, Please complete the table below | SP | Yes | Right now in the system, we do not have a feature of having half text as normal and half text as bold in full sentence. Development change need to be done.  Ok  Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT MONITORING |  | If Continued then No action require and if Discontinued than Specify reason field require. However, in CRF screen it’s not getting differentiated appropriately  Similarly Enter the details in Patient completion status should be with Specify but different box is created | SP | Yes | Followed as per the CRF .Modified the design  Resolved | Rajitha G 06/10/2017 |
| VITAL SIGNS | No | Heart Rate: should not accept more than three numeric digits. The field is accepting more than three digits. |  | YES | Max length has fixed to 3  Resolved | Rajitha G 06/10/2017 |
| VITAL SIGNS | No | Respiratory Rate: should not accept more than two numeric digits. The field is accepting more than two digits. |  | YES | Max length has fixed to 2  Resolved | Rajitha G 06/10/2017 |
| VITAL SIGNS | No | For one field data is change and there are more than one field on the form then we have to give reason for all the fields. This is very time consuming. |  | YES | Need Clarification from Client  When Data is entered and saved for first time, then when data is change reason of change is not asking for that particular field  Resolved | Rajitha G 06/10/2017 |
| VITAL SIGNS | No | Body Temperature: We can enter any numeric value in this field. |  |  | Changed decimal data type to Numeric  Unable to enter 108.1 or 37.1  **Able to update more than one decimal** | Rajitha G 06/10/2017  Updated to Decimal |
| VITAL SIGNS |  | Only one decimal should be allowed in numeric. However, more than one decimal that is 35….. is allowing to enter and save | SP | Yes | Not feasible. Confirmed by Dev Team .Can configure edit check for that(Suggestion)  OK | Rajitha(06/10/2017) |
| VITAL SIGNS |  | In Blood pressure decimal should not be allowed however, its allowing to update decimal EG: 1.2 | SP | YES | Changed the data type from Decimal to Numeric  Resolved | Rajitha G 06/10/2017 |
| PHYSICAL EXAMINATION | No | For **Any abnormal finding(s) present** [Please cross (**X**)] sentence **Any abnormal finding(s) present** should be in bold letters and **x** should be also in bold. |  | YES | Right now in the system, we do not have a feature of having half text as normal and half text as bold in full sentence. Development change need to be done.  Please Bold complete line that is **Any abnormal finding(s) present [Please cross (X)]**  Resolved | Rajitha G 06/10/2017  Updated |
| PHYSICAL EXAMINATION | No | For Body system others, Other specify field should be present on the form |  | YES | Textbox have been added for the others  Resolved | Rajitha G 06/10/2017 |
| LABORATORY INVESTIGATIONS |  | In original crf Lipid profile is not given no as 4. Please check. |  | YES | Removed point 4 from CRF  Resolved  Bold below two variable  Viral loads  CD4 counts  Resolved | Rajitha G 06/10/2017  Updated |
| LABORATORY INVESTIGATIONS |  | Observed values field is created as Alpha numeric. However, it’s require to create Numeric field.  Length of field need to confirm from Client | SP | Yes | Changed the String Datatype to Numeric for all the observed values  Unable to add decimal in field EG 10.2  **Able to update more than one decimal** | Rajitha G 06/10/2017  Updated to Decimal Types |
| SELECTION CRITERIA | No | Inclusion Criteria and Exclusion Criteria: **both title should be bold on the form.** |  | YES | Title has been changed to Bold  Resolved | Rajitha(06/10/2017) |
| INCLUSION CRITERIA | No | In inclusion criteria no. 3 options should be put in bullets. Check the original crf form. |  | YES | Modified the panel as per the discussion with the client  Resolved | Rajitha(06/10/2017) |
| INCLUSION CRITERIA | No | (\*V11I, V32I, L33F, I47V, I50V, I54L, I54M, T74P, L76V, I84V and L89V) needs to be included in inclusion criteria no. 3 only | SP | YES | Modified the panel as per the discussion with the client  Resolved | Rajitha(06/10/2017) |
| SELECTION CRITERIA | No | Inclusion Criteria and Exclusion Criteria: In the note few points are in the bold. Please check the original crf form. |  | Yes | Right now in the system, we do not have a feature of having half text as normal and half text as bold in full sentence. Development change need to be done.  OK  Resolved | Rajitha  (06/10/2017) |
| All forms | No | All notes are in italics. |  | YES | No Feature Exists Right now. Development Change  OK  Resolved | Rajitha  (06/10/2017) |
| URINE PREGNANCY TEST | No | In Visit 2 after AE monitoring **URINE PREGNANCY TEST (If required**) form is missing |  | YES | Added the form  Resolved | Rajitha(06/10/2017) |
| VISIT 2 Baseline Visit |  | Study drug and Subject diary retrieval is added. However, it’s not require as per draft CRF | SP | YES | Removed  Resolved | Rajitha(06/10/2017) |
| SUBJECT SELECTION |  | Has the Patient fulfilled the selection criteria? Yes or NO  Its allowing to select the both. However, it should allowed any one | SP | YES | Panel design modified  Keep below field together  If yes, enroll the patient and assign the Patient Number.  Patient Number allotted  Resolved | Rajitha(06/10/2017)  Updated |
| SUBJECT SELECTION |  | Patient Number allotted: is require to create 4 digit that is numeric. However, field is alphanumeric | SP | YES | Changed that field as Numeric  Resolved | Rajitha(06/10/2017) |
| STUDY DRUG AND SUBJECT DIARY RETRIEVAL  STUDY DRUG DISPENSING | No | STUDY DRUG AND SUBJECT DIARY RETRIEVAL for signature Yes/No. option should be there?  *Signature is require in form of password entering for more detail, can we discuss on call* |  | YES | Modified as per the discussion with client  Resolved | Rajitha(06/10/2017) |
| LABORATORY INVESTIGATIONS |  | In LABORATORY INVESTIGATIONS2 update CRF format For Differential count and Lipid profile as per  LABORATORY INVESTIGATIONS1 | SP | YES | Not Understandable  Please create LABORATORY INVESTIGATIONS2 format exactly same as LABORATORY INVESTIGATIONS1 format  Resolved |  |
| LABORATORY INVESTIGATIONS2 |  | LABORATORY INVESTIGATIONS2:  Change test header format EG: Hematology Examination and Renal Function Test as per LABORATORY INVESTIGATIONS1 form | SP | YES | Not Understandable  Please create LABORATORY INVESTIGATIONS2 format exactly same as LABORATORY INVESTIGATIONS1 format  Resolved |  |
| LABORATORY INVESTIGATIONS | No | All observed values are accepting any number. Please check as per the Lab ranges. |  | Yes | All the observed values changes to Numeric  LABORATORY INVESTIGATIONS2 form change to numeric. Also it should allow to update decimal that is value like 10.25  **Able to update more than one decimal** | Rajitha(06/10/2017)  Updated to Decimal Data Type |
| STUDY DRUG DISPENSING | No. | Please check if completed by and sign fields are required. |  | YES | Removed as per the discussion with client  Resolved | Rajitha(06/10/2017) |
| STUDY DRUG DISPENSING |  | In Treatment period Week 12+-2 days (Visit 3) field included as below in screen however remove this field from this visit  Is the subject Diary dispensed to the subject? | SP | YES | Modified as per the client suggestion  Please removed “Is the subject Diary dispensed to the subject?” Field from this visit  Resolved | Rajitha(06/10/2017)  Removed |
| SUBJECT DIARY DISPENSING  STUDY DRUG COMPLIANCE |  | Form included in eCRF screen but in draft its missing. Please confirm any comment received from client to add form | SP | Yes | Modified as per the discussion with client  Need to highlight to CIPLA team | Rajitha(06/10/2017) |
| STUDY COMPLTION STATUS | No | This form is not required for the visit TREATMENT PERIOD WEEK 12 ± 2 days. |  | YES | Separate visit have been added  Resolved | Rajitha(06/10/2017) |
| TREATMENT PERIOD WEEK 24 ± 4 days |  | Folder name is given as TREATMENT PERIOD WEEK 24 **+** 4 days  Change to  TREATMENT PERIOD WEEK 24 ± 4 days | SP | YES | Modified  Resolved | Rajitha(06/10/2017) |
| TREATMENT PERIOD WEEK 24 ± 4 days |  | For visit field label is added as TREATMENT PERIOD WEEK 12 ± 2 days. Please change 12 ± 2 days to 24 ± 4 days | SP | YES | Updated the Visit Name  Issue is still ongoing  Resolved | Rajitha(06/10/2017)  Updated |
| PREVIOUS AND CONCOMITANT MEDICATION FORM  AE form  Serious AE form  Study Drug compliance |  | Please remove mention forms from Visit folder. It do not included in specific visit. | SP | YES | Modified as per the discussion with client  Resolved | Rajitha(06/10/2017) |
| PREVIOUS AND CONCOMITANT MEDICATION FORM | No. | Please adjust the title. |  | Yes | We will do later after configuring the edit checks because of the development change  Please clarify. | Rajitha(06/10/2017) |
| PREVIOUS AND CONCOMITANT MEDICATION FORM |  | In field please add bracket detail below the main field label  EG:  **Drug Name**  (Generic preferred; if combination product, use brand name) | SP | Yes | We will do later after configuring the edit checks because of the development change  Please change the field header | Rajitha(06/10/2017) |
| PREVIOUS AND CONCOMITANT MEDICATION FORM | No. | Dose and frequency drop down is created with no field to add.  Drop down included in field are just example keep alphanumeric free text field. |  | YES | Modified the dropdowns to textboxes  Resolved | Rajitha(06/10/2017) |
| PREVIOUS AND CONCOMITANT MEDICATION FORM |  | Start and End date can be partial date on this form. Please create partial date field. | SP | No | Feature need to be implemented \_Dev Change  Awaiting for update | Rajitha(06/10/2017) |
| PREVIOUS AND CONCOMITANT MEDICATION FORM |  | Add new logline option is not available in this form | SP | YES | Add more button is displaying.Please Check  Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT FORM (INITIAL)  ADVERSE EVENT DETAIL (FOLLOW-UP)  SERIOUS ADVERSE EVENT DETAILS |  | This form should create in logline/Row format. Like medical history form | SP | YES | Modified  Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT FORM (INITIAL)  ADVERSE EVENT DETAIL (FOLLOW-UP)  SERIOUS ADVERSE EVENT DETAILS |  | ‘A. Description of the Adverse Event:’ and ‘Please list ONE event per column Give the Diagnosis as far as possible’ should be in one field  Similarly in SAE form too | SP | YES | Modified  Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT FORM (INITIAL) | No. | “Select” is reflecting in dropdown can we keep that as blank |  | YES | Need to discuss  NO action require Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT FORM (INITIAL) | No. | **G. Action taken**  (Several statements are possible)  Please bring all point one below other  EG:  1. - None  2. - Dose of study drug reduced  3. - Study drug temporarily discontinued  4. - Study drug permanently discontinued |  | YES | Change from horizontal position to Vertical  Resolved | Rajitha G 06/10/2017 |
| ADVERSE EVENT FORM (INITIAL)  ADVERSE EVENT DETAIL (FOLLOW-UP) |  | For Stop date add field label, field label is blank for stop date | SP | YES | Modified the panel as per the discussion with client  Resolved | Rajitha G 06/10/2017 |
| SERIOUS ADVERSE EVENT DETAILS |  | Format should be as log line format. Grid format and there can be more than three events. More events should be able to add. Please discuss with sciformix team about the format. |  | YES | Modified  Resolved | Rajitha G 06/10/2017 |
| SERIOUS ADVERSE EVENT DETAILS |  | Time format should be applied it’s allowing to save 28:22 also (time format 23:59 is allowed) |  | Yes | Modified  **Issue ongoing able to update 28:99**  Resolved  Query added | Rajitha G 06/10/2017 |
| SUBJECT COMPLETION STATUS |  | \*In index its reflecting as study drug compliance. | SP | YES | Modified  Resolved | Rajitha G 06/10/2017 |
| SUBJECT COMPLETION STATUS | No. | For To be completed only for patient’s prematurely terminated drop down menu please add other option. |  | Yes | Modified  Issue still ongoing “other” not reflecting in drop down  **Other Specify field is also require**  Resolved | Rajitha G 06/10/2017  Updated |
| PRINCIPAL INVESTIGATOR’S STATEMENT | No. | Please check for investigator signature field. Please discuss. |  | YES | Remove the Form  Resolved | Rajitha G 06/10/2017 |
| APPENDIX I | No. | **APPENDIX I and ii is not required. Please discuss.** |  | YES | Removed the panels  Resolved | Rajitha G 06/10/2017 |
| AUDIO CONSENT  INFORMED CONSENT  ECG |  | Time Field is allowing to update 25 also. Please create field in time format |  | YES | **Issue still ongoing**  Resolved  Query added | Rajitha G  06/10/2017 |
| ~~DEMOGRAPHY~~ |  | ~~Date of Birth needs to be created as Partial Date~~ |  |  | **~~Issue still ongoing~~** | ~~Already Reported~~ |
| ADVERSE EVENT FORM (INITIAL)  ADVERSE EVENT DETAIL (FOLLOW-UP)  SERIOUS ADVERSE EVENT DETAILS |  | Update field label require  Currently its like  A.Description of the Adverse Event: Please list ONE event per column Give the Diagnosis as far as possible  Change to  **A.Description of the Adverse Event:**  Please list ONE event per column Give the Diagnosis as far as possible |  |  |  | Rajitha G  06/10/2017 |
| SERIOUS ADVERSE EVENT DETAILS |  | 10. Signature and Date of the  Investigator  Date (dd / mm / yyyy) field is missing |  | YES | Resolved |  |
| PRINCIPAL INVESTIGATOR’S STATEMENT form |  | Unable to see and add PI statement at subject level.  12-Oct-2017: Password is not asking for this form or any field at time of submitting |  |  |  |  |
| Unscheduled visit |  | Please clarify. |  |  |  |  |
| ADVERSE EVENT MONITORING |  | Able to select both Continued and Discontinued |  |  |  |  |