Demonstration and Use Case

Erasmus MC: Data Capture Systeem

Data Capture Tender demonstration and Use Case

We ask all vendors to present their solution following a predefined use case.
This use case will allow the Erasmus MC to objectively and fairly compare the different demonstrations from different vendors.
It has been set-up to represent many but not all requirements from the Erasmus MC and to allow for evaluation of how intuitive, easy to use and responsive the solution is.
In order to go through the used case, we ask each vendor to set-up a test environment that meets the conditions as described in the **Prerequisite (A)**, and during the presentation perform the steps as described in the **Script for the demonstration (B)**.

The presentation will be evaluated based on the following points:

- Have all parts of the Use Case been discussed in the demonstration;
- How user-friendly is the Data Capture solution; Pay attention to intuitiveness, responsiveness (speed) and effectiveness (number of clicks / actions).

A. Prerequisite For the demonstration use an existing environment with a study that meets these conditions:	
01.	A visit schedule exists with at a minimum the following forms: a. Adverse Event Form (that makes use of a dictionary) containing at a minimum the following fields: - Adverse Event description (searchable) - Adverse Event Code (automatically filled from the dictionary) - Start date - Stop date - Serious AE b. Concurrent Medication Form (that makes use of a dictionary) containing at a minimum the following fields: - Name of drug, medication or therapy (searchable) - Code (automatically filled from the dictionary) - Start date - Ongoing - Stop date c. One or more forms containing: - Cross forms check - Radio buttons - Drop down lists - Check boxes - Check boxes - Text fields - Visual Analogue Scale
02.	Multiple sites have been set-up.
03.	At a minimum 10 patients have been included.
04.	At a minimum 20 forms have been completed.
05.	Variable block size randomization has been set up using the following parameters: a. Two treatment groups (‘Arm A’ and ‘ Arm B’); b. Stratification on ‘Site’ and ‘ Gender’ (Male, Female).
06.	An account for a system administrator his available.
07.	An account for a user with the rights to design, test and deploy a new form in the existing study is available.
08.	A account for a user with the rights to Review data, Raise queries, print, export and view the audit trail is available.

B. Script for the demonstration	
01.	Log in as a Designer / System administrator.
02.	Design a new form (field for field) according to the specifications as described in **Requirements of form to be designed during the presentation (C)**.
03.	Show how all aspects of the form can be tested effectively without bringing it in to the production environment yet. Focus on: a. Ranges b. Error messages c. Layout d. check if the right conditions trigger the correct error messages
04.	Show how the Study design (Meta data) can be reported / documented
05.	Deploy the form to the pre-existing (see Prerequisite for details) production environment .
06.	Add a new Data Entry user with rights to enter data for an individual site.
07.	Show how users receive authorizations within the system.
08.	Show how an overview of accounts and corresponding rights van be reported.
09.	Log out.
10.	Login as an Data Entry User with the newly created user account.
11.	Enroll a new study subject in the study.
12.	Make sure the subject is randomized.
13.	Elaborate on how 'responsive' the system is with regards to: a. use of different PC screen sizes; b. use of Tablets; c. use of mobile phone screens.
14.	Enter data in the newly designed form and show that/ how: a. required fields are flagged; b. hard ranges are respected; c. soft ranges are addressed; d. cross-field checks are triggered; e. keyboard shortcuts can be used as a full alternative to mouse use; f. previously entered values can be changed and cleared; g. reason for change is recorded; h. values can be marked as missing (e.g. Not applicable, Not ascertained, Missing, Unknown).
15.	Enter data in some of the other forms and show that/ how: a. cross-forms checks are triggered; b. show how an Adverse Event is recorded; c. show how the dictionary can be searched and used to find the right term and underlying code; d. the Visual Analogue scale is used; e. files can be securely uploaded.
16.	Show several reports that will help the Data Entry staff in performing their work effectively.
17.	Log out.
18.	Log in as a data manager/ reviewer and show that / how: a. navigation between sites and subjects works;

	b. filters can be (re-)used to find specific subjects/ data; c. valuable reporting capabilities for the user; d. manual queries can be raised (Raise at least 4 queries that can be shown in the Data Entry mode); e. the history of individual fields can be shown with maximum two mouse clicks.
19.	Log out.
20.	Log in as the Data Entry user again and show that / how: a. the user is notified about new/ pending queries; b. queries are presented to the user; c. queries can be answered; d. queries can be answered by selecting predefined answer (e.g. 'Not applicable'); e. how data can be deactivated; f. data is marked as complete.
21.	Elaborate / show the different ways external data can be brought into the Data Capture Solution (e.g. Import / Interfacing), pay attention to: a. different data formats; b. security; c. the audit trail; d. (Error) logging.
22.	Log out.
23.	Log in as a data manager again and show that / how: a. queries can be re-raised; b. data can be marked as Source Data Verified; c. forms / subjects can be locked for data entry; d. the audit trail of the entered data (user, date and time stamp, including changes and reason for change); e. the audit trail of the study design; f. who viewed the data; g. show how uploaded files can be downloaded.
24.	Elaborate on the locking possibilities of the system: a. sites (new subject inclusion); b. sites (entering new data); c. forms; d. entire study.
25.	Show how the data and any changes can effectively and efficiently be reviewed.
26.	Show how manual queries can be raised and reviewed.
27.	Show how answers to queries can be accepted and rejected, and how a query can be re-raised.
28.	Show several reports that will help the Data Manager in performing their work effectively.
29.	Show how data can be exported from the system.
30.	Elaborate / show the different ways data can be exported / extracted from the system, pay attention to: a. different data formats; b. integrity checking on imported data; c. meta data; d. security; e. the audit trail.
31.	Show the different filter options for study data.
32.	Show how repetitive data (e.g. AE and Medications) is exported.
33.	Show the audit trail of all steps performed:

	a. designing the form; b. adding user; c. entering data; d. deactivating data.

C. Requirements of form to be designed during the presentation

Please design, during the presentation, a new form that contains the following fields, ranges, and edit checks.

Systolic BP : _____ (in mmHg)
(Checks: only accept values between 0-400, Give warning “Are you sure” when < 90 or >140Soft range)

Diastolic BP : _____ (in mmHg)
(Checks: Give warning “This is not possible” when DiastolicBP > SystolicBP)

Height :_____ (in cm)
(Checks: only accept values between 0-300)

Weight :_____ (in kg)
(Checks: only accept values between 0-500)

BMI : _____
(Read-only with automatically calculation [Weight (kg)]/[Height (m)]^2)

Which pets do you have: _____
(Multiple select, valid answers are: ‘Dog’, ‘Cat’, ‘Mouse’, ‘Other’)

Please specify other pet(s): _____
(Only in the case ‘Other’ is selected for the previous question)