Study Title: Respiratory sinus arrhythmia pacing post-CABG surgery in patients with HFrEF **Short-title/acronym:** RSA-PACE	**IRAS reference:** 315761 **MHRA reference:** CI/2024/0036/GB **Portfolio CPMS:** CARD 53420
Chief Investigator: Prof Zaheer Yousef	**REC reference:** 24/YH/0110
Sponsor Reference Number: Cer22/01	**Sponsor:** Ceryx Medical

RSA-PACE REDCap Training

RSA-PACE uses REDCap as both the database for study data and an electronic case report form (eCRF). Data can be entered directly by study participants into REDCap or recorded on paper CRFs and transcribed into the system.

To access REDCap:

- On a Cardiff and Vale UHB PC: https://rwmbvsrvredca_p1.cymru.nhs.uk.
- All other PCs: https://integration2.cavuhb.nhs.wales.

1 Account Creation

To access REDCap, you will need a Cardiff and Vale REDCap account. Previous REDCap logins from other locations will not work as each REDCap service requires a unique login. To request an account, email CEDAR at RSA.PACE.Cav@wales.nhs.uk.

Once your account is created, you will receive a username and password via email. If you are outside of Cardiff and Vale you will have to change the first part of the

URL sent to you in this email (see above). You will then be assigned a role within the RSA-PACE project, granting access to data collected at your site.

2 Data Entry

REDCap provides a training video on data entry, which you can access here.

2.1 REDCap basics

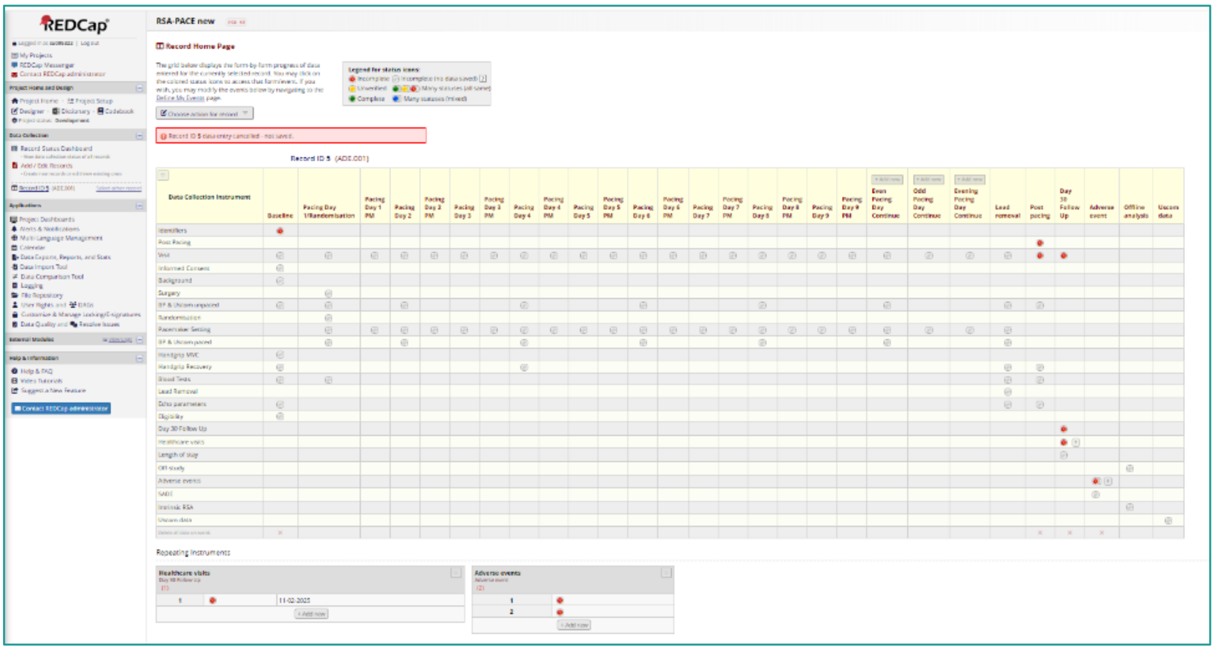
In REDCap, each study visit, or separate data collection activity, is called an Event. Each Event uses several Forms to collect the data for that visit. For example, the Baseline Visit Event has several Forms that cover all the data collected in the Baseline, Baseline Echo, and Eligibility CRFs.

A Form groups the data logically, so that the same Form can be re-used if the same set of data is collected at different times. For example:

- Visit Form: dates and times, verbal consent, AEs since last visit.
- Background Form: date of birth, sex, demographics, co-morbidities, etc.
- Blood Tests Form: haemoglobin, eGFR, NT-proBNP, etc. (as required)

Forms are included in each Visit they are needed. For example, pacemaker settings are collected multiple times during this study, so there is a Pacemaker Form that collects the same sets of data in each of those Events/Visits.

2.2 Creating a New Participant Record



On the left-hand side is a menu. Click on Add / Edit Records. From this page you can create a new participant Record using 'Add new record'. This opens up a Record Home Page with a new Record ID. Record ID is a number automatically assigned by REDCap, and cannot be changed. When you enter the participant information you will be able to see the RSA-PACE participant ID next to this, e.g. "Record ID 5 (CAV.003)".

2.3 Record Home Page

The Record Home Page (Figure 1) shows the Events (Visits) across the top and the Forms down the side. Each Form for each Visit is shown by a grey circle on the table. The colour of the circle changes with data entry status (Figure 2):

- Grey Circle: No data entered.
- Red Circle: Incomplete.
- Yellow Circle: Unverified.
- Green Circle: Complete.
- Blue: mixed status (where there are several copies of the same form)

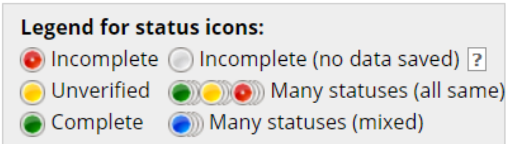


Figure 2: Form statuses

The table is quite large, so you will have to scroll right and down to see the whole set of Visits and Forms.

Start data entry for a new patient by clicking the **'Identifiers'** Form for the Baseline Visit at the top left of the table. Enter the information for the Participant – site, ID number and initials. This is the same information as across the top of each paper

Figure 1: Record Home Screen

CRF (if being used). At the end of the Identifiers Form, change the Status to '**Unverified'**. Then either 'Save and Exit Form' to go back to the Record Home Page, or 'Save and Go To Next Form' to proceed with the data entry for the Baseline Visit. 'Cancel' will exit the Form without saving any data.

Do not press 'Enter' on the keyboard, as this will Save and Exit the Form.

You can also navigate through the Forms for each Visit/Event by using the menu on the left-hand side (Figure 3).

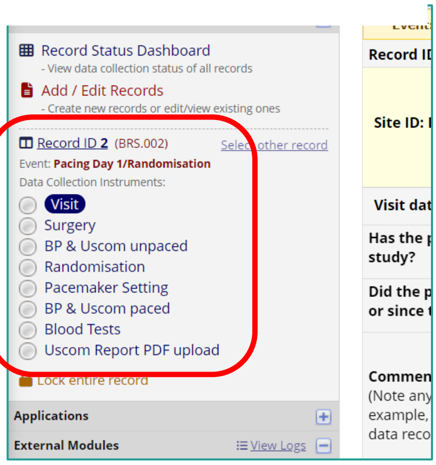


Figure 3: Side menu for Form navigation

2.4 Data Entry - Forms

Participant ID and the Visit (Event) name are always displayed at the top of each screen/Form (Figure 4).

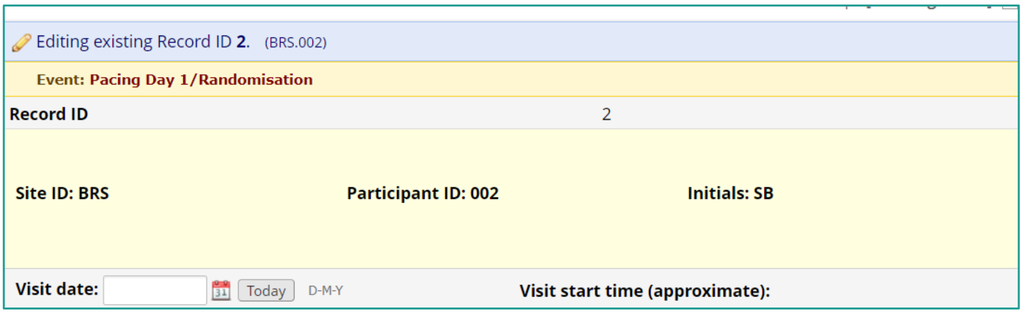


Figure 4: Header for each Form

Use the 'Tab' key to navigate fields within a Form. Some fields depend on previous answers (e.g., if you answer "Yes," additional questions appear). These fields will appear and disappear based on your input.

Enter data exactly as it appears on the CRF or source documents, paying attention to any data entry rules. For instance, if the instructions say "1 decimal place," ensure you follow this format. Fields may have acceptable ranges, and entering values outside these will trigger a message suggesting that you change them. However, if the data is correct you can ignore the warning and save the value.

Once all data on a Form is entered, mark the status as 'Unverified.' (After monitoring checks, it will be updated to 'Complete.')

2.5 Mandatory Fields and Missing Data

Some fields are mandatory and must be completed. You cannot Save the Form until these fields are complete.

Do not leave any fields blank. If data is missing for some reason use the 'M' missing data button on the left of each field (Figure 5).

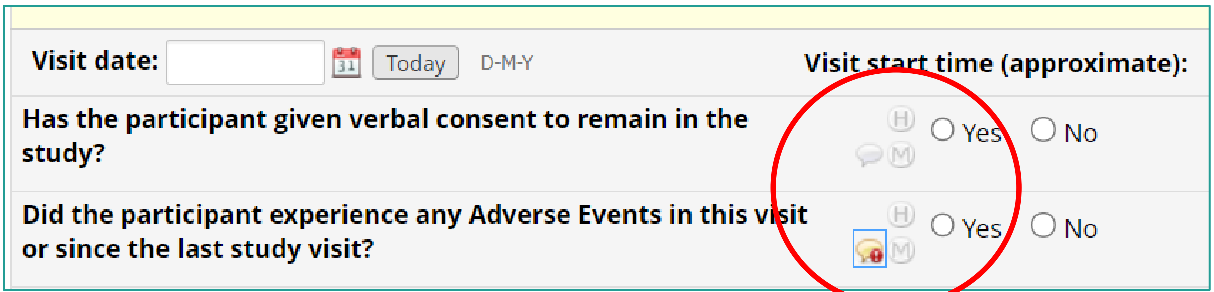


Figure 5:'M'issing Data, 'H'istory and Data Query buttons for each field

The available codes can also be directly typed into the box. Only use these codes:

- ND – Test/assessment not done.
- NAP – Field not applicable.
- NAV – Test done, but data unavailable.
- DR – data removed (only to be used on instruction from the CRO, e.g. when data is considered to be unreliable)

NEW

To change a missing value to actual data, click the 'M' icon and select 'Clear value.'

2.6 Comments

Each Form includes a 'Comments' box for noting anything significant about that section of the data collection.

2.7 Saving and Updating Data

Data is only saved after clicking one of the 'Save' options at the bottom (or top right) of the Form. Unsaved changes will be lost if you Exit the Form.

Saved data can be updated later, but you must provide a reason for any changes of value after you have Saved them. For instance, if updating "Not known" to "20.5," use a reason such as "Data not known initially" or "Source data located."

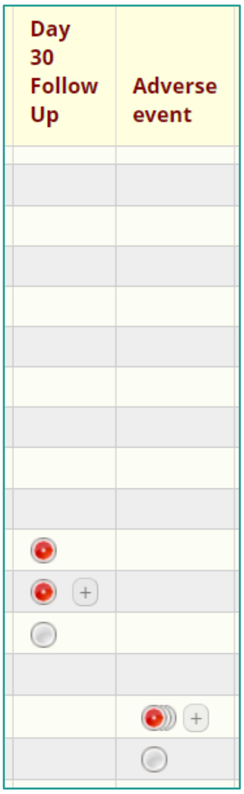
To keep an audit trail, all data changes are logged and linked to your account. The change history can be viewed by clicking the 'H' button on the left of the field (Figure 5).

If no changes are made, click 'Cancel' instead of 'Save' to avoid creating unnecessary audit entries.

All data entry and changes are logged, including details of what was changed, who made the change, and when. This ensures transparency and accountability. Monitoring visits will verify the data against paper CRFs and/or source documents.

2.8 Adding and Managing AEs

If an AE has occurred, select 'Yes' on the AE question in the appropriate Visit Form. Then open the Adverse Event Form from the Record Home Page. You must create a new instance of an Adverse Event for each AE that a participant has. Add additional AEs by clicking the [+] on the right of the circle (see right) or selecting '+ Add new' in the Repeating Instruments box at the bottom of the Home Record Page (Figure 6Figure 6). Participants may have several AEs that are consecutively numbered.



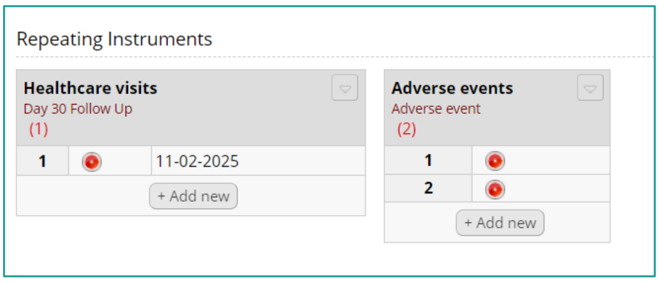


Figure 6: Multiple instances of AE and Healthcare Visit Forms at base of Home Record Page

Edit AEs by clicking the corresponding circle on the table or the AE Repeating Instrument.

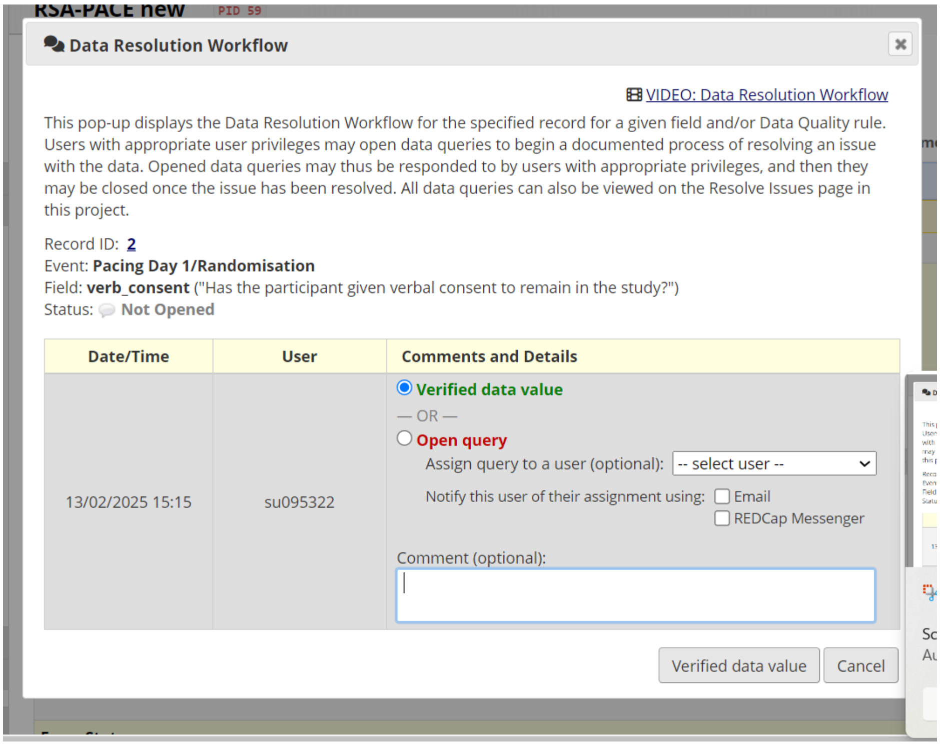
2.9 Day 30 follow-up – multiple Healthcare Visits & Length of Stay Forms

If there are no healthcare visits reported by the patient or on the patient notes, you only have to complete the Day 30 Form. If there are any reports of healthcare consultations, please complete a new Healthcare Visit Form for each report of a Visit. There should be separate reports for each patient reported visit and each visit identified from the patient's notes. Creating multiple Healthcare Visit Forms works the same way as creating multiple Adverse Event Forms.

Length of stay is reported from the date of surgery until initial discharge. Separate records are needed when patients change between different levels of care. So, a new Length of Stay Form is created for each type of ward/unit that the participant stayed on after their surgery. This works the same way as creating an Adverse Event Form.

2.10 Data Queries

If data is thought to be potentially wrong, or is missing without a reason given, a Data Query can be Opened (called Data Resolution Workflow in REDCap). This opens a pop-up window in which the query can be described and assigned to a user for a response. That user can be notified via email or a message in REDCap or both. REDCap Messenger is in the top left of the REDCap screen.



Any data field with an open query has a red exclamation mark (!) next to it in the Data Query button. Users may respond to the query by clicking on the link in the message. They may update the value, and/or close the query depending on what user rights they have. Most users can open and respond to a query, but only CEDAR and Avania staff can close them. A reason must be entered whenever data is changed.

3 Uploading files

3.1 REDCap Upload

Data downloads from the Uscom device have to be uploaded to REDCap. At the end of the measurements (3 or 6 recordings) a PDF Report from each recording is created. At the end of all the Uscom recordings (either after the Post Pacing Visit or when the participant is withdrawn) a CSV data file for the participant is exported. Each PDF and the CSV data file are uploaded to the REDCap database.

1. Ensure files are correctly named.

   PDFs: **[Trial_ID]-[Study visit name]-[Paced/Unpaced]-[Recording number]** NEW
   - E.g. "CAV001-PD1-Paced-1"

   CSVs: **[Trial_ID]-[Uscom Data]**
   - E.g. "CAV001-Uscom Data"

2. From the Record Home Page, open the appropriate form:
   - **Uscom Report PDF:** Each visit where Uscom is performed has separate forms for paced and unpaced recordings. Upload all three recordings for each visit.
   - **Uscom data CSV:** A single form is available towards the bottom of the Record Home Page on the Post Pacing visit.
3. Click 'Upload file' to open the upload box.
4. Click the 'Choose File' button to open File Explorer.
5. Locate the file (either on the USB stick or saved on the PC) and click 'Open'.
6. In the upload box, click the blue 'Upload file' button. The file will now be uploaded to REDCap.

3.2 ECG report uploads NEW

1. You can upload up to 5 ECG PDF reports per participant. These will include:
   - 'Baseline'
   - during 'Pacing'

- ‘Home’ recording (where used)
- ‘PostPacing’.

   A participant may have more, for example if an ECG device needs to be replaced during data recording.

2. For sites using ECG On Demand, download the standard PDF format.
3. Ensure files are correctly named: “**StudyID-Visitname-startdate**”.
   Startdate is the date that the recording started, and should be in the format DD-MM-YYYY. So, for the in-patient pacing recording, use the date of PD1.
   E.g. “CAV005-PD1-14-12-2024.PDF” “BRI009-PP-05-08-2025.PDF”
4. From the Record Home Page, go to the ECG PDF Report Upload Form (near the bottom).
5. Click ‘Upload file’ to open the upload box.
6. Click the ‘Choose File’ button to open File Explorer.
7. Locate the file (either on the USB stick or saved on the PC) and click ‘Open’.
8. In the upload box, click the blue ‘Upload file’ button. The file will now be uploaded to REDCap.