# Data Entry and REDCap Database User Guide

Version 1.2

www.space-flot.com

*This guide should be used in conjunction with the SPACE-FLOT study protocol.*

**Contents:**

# 1. Pre-requisites before starting data entry

*1.1. Basic pre-requisites*

- Research office approval to conduct study

- Maintain patient confidentiality at all times

- A valid and active institutional email

- A validated, verified and password protected REDCAPS account

- Granted approval by your hospital lead to commence data entry

*1.2. Identifying eligible patients*

Eligibility criteria for inclusion into SPACE-FLOT are:

     a.  All consecutive patients from January 1st, 2017 to December 31st, 2021 who are

     b.  Age ≥18 years old

     c.  Had gastric, adenocarcinoma and/or gastro-oesophageal cancer

     d.  Had preoperative FLOT chemotherapy

     e.  Had surgical resection

These patients can be identified in a number of ways. This will be institution based. These methods include:

- Surgical unit databases

- Medical oncology unit databases

- Ask your Health Information Systems/Medical Records department to run a search for the following Australian Classification for Health Intervention (ACHI) codes between the periods 01/01/2017 to 31/12/2021 inclusive

| Operations | Codes | Block |
|---|---|---|
| Oesophagectomy | 3054500, 3054501, 3055000, 3055001, 3054100, 3054101, 3053500, 3053600, 3053601, 3029400 | 858, 859, 860, 861 |
| Subtotal gastrectomy | 3052300 | 879 |
| Distal gastrectomy | 3051800, 3051801, 3051802 | 875 |
| Total gastrectomy | 3052100, 3052400 | 879 |

- If none of the above apply, we suggest you speak with your Health Information Systems/Medical Records staff and inquire about generating a patient list for all oesophagectomy, subtotal, distal, and total gastrectomy performed between the periods 01/01/2017 to 31/12/2021 inclusive

*1.3. Setting up study ID*

After generating your list of patients, create study IDs in the Patient identification log. The Patient identification log is a separate document held by the Site lead at your institution which links the Study ID, REDCap ID, and patient identifiers (e.g. UR, name, DOB). The Study ID will need to be entered into REDCap (see below), and the REDCap ID generated automatically from REDCap will need to be entered into the Patient identification log. This log will allow re-identification of patients for data entry and data cleaning purposes.

Format of study ID: Country, hospital initials, study number (serially incrementing per patient)

| Country | Centre | Study ID |
|---|---|---|
| Australia – ACT | Canberra Hospital | AUCH001, AUCH002, AUCH003, etc |
| Australia – NSW | The Royal Northshore Hospital | AURNSH001, AURNSH002, AURNSH003, etc |
| Australia – NSW | Bankstown/Liverpool Hospital | AUBLH001, AUBLH002, AUBLH003, etc |
| Australia – QL | Royal Brisbane Women's Hospital | AURBWH001, AURBWH002, AURBWH003, etc |
| Australia – QL | Princess Alexandra Hospital | AUPAH001, AUPAH002, AUPAH003, etc |
| Australia – SA | Flinders Medical Centre | AUFMC001, AUFMC002, AUFMC003, etc |
| Australia – SA | Lyell McEwin Hospital | AULMC001, AULMC002, AULMC003, etc |
| Australia – SA | Royal Adelaide Hospital | AURAH001, AURAH002, AURAH003, etc |
| Australia – Tas | Royal Hobart Hospital | AURHH001, AURHH002, AURHH003, etc |
| Australia – Tas | Launceston General Hospital | AULGH001, AULGH002, AULGH003, etc |
| Australia – Vic | Peter MacCallum Cancer Centre | AUPMCC001, AUPMCC002, AUPMCC003, etc |
| Australia – Vic | Austin Hospital | AUAH001, AUAH002, AUAH003, etc |
| Australia – Vic | St Vincent's Hospital | AUSV001, AUSV002, AUSV003, etc |
| Australia – Vic | Northern Hospital | AUNH001, AUNH002, AUNH003, etc |
| Australia – Vic | Box Hill Hospital | AUBHH001, AUBHH002, AUBHH003, etc |
| Australia – Vic | Monash Medical Centre | AUMMC001, AUMMC002, AUMMC003, etc |
| Australia – Vic | Western Hospital | AUWH001, AUWH002, AUWH003, etc |
| Australia – Vic | Bendigo Hospital | AUBH001, AUBH002, AUBH003, etc |
| Australia – WA | Fiona Stanley Hospital | AUFSH001, AUFSH002, AUFSH003, etc |
| Canada - Montreal | Montreal General Hospital | CAMGH001, CAMGH002, CAMGH003, etc |
| Canada - Toronto | Ontario Health | CAOH001, CAOH002, CAOH003, etc |
| France | Lille University Hospital | FRLUH001, FRLUH002, FRLUH003, etc |
| India | Christian Medical College | INCMC001, INCMC002, INCMC003, etc |

| Ireland | Mercy University Hospital | IRMUH001, IRMUH002, IRMUH003, etc |
|---|---|---|
| Ireland | St James Hospital | IRSJH001, IRSJH002, IRSJH003, etc |
| Malaysia | CENGILD GI Medical Center | MACMC001, MACMC002, MACMC003, etc |
| New Zealand | Christchurch Hospital | NZCH001, NZCH002, NZCH003, etc |
| New Zealand | Middlemore Hospital | NZMH001, NZMH002, NZMH003, etc |
| New Zealand | Dunedin Hospital | NZDH001, NZDH002, NZDH003, etc |
| New Zealand | Palmerston North Hospital | NZPNH001, NZPNH002, NZPNH003, etc |
| New Zealand | North Shore Hospital | NZNSH001, NZNSH002, NZNSH003, etc |
| New Zealand | Auckland City Hospital | NZACH001, NZACH002, NZACH003, etc |
| New Zealand | Wellington Regional Hospital | NZWRH001, NZWRH002, NZWRH003, etc |
| Singapore | National University Cancer Institute of Singapore | SGNUH001, SGNUH002, SGNUH003, etc |
| Sweden | Karolinska Comprehensive Cancer Centre | SWKCCC001, SWKCCC002, SWKCCC003, etc |
| The Netherlands | Erasmus University Medical Center | NEEUMMC001, NEUMMC002, NEUMMC003, etc |
| The Netherlands | Utrecht Medical Centre | NEUMC001, NEUMC002, NEUMC003, etc |
| The Netherlands | Amsterdam University Medical Center | NEAMC001, NEAMC002, NEAMC003, etc |
| UK | Norfolk and Norwich University Hospital | UKNNUH001, UKNNUH002, UKNNUH003, etc |
| UK | Queen Elizabeth Hospital | UKQEH001, UKQEH002, UKQEH003, etc |
| UK | Royal Victoria Infirmary | UKRVH001, UKRVH002, UKRVH003, etc |
| UK | Oxford University Hospital | UKOUH001, UKOUH002, UKOUH003, etc |
| UK | Imperial College London | UKICL001, UKICL002, UKICL003, etc |
| UK | University Hospitals Plymouth | UKUHP001, UKUHP002, UKUHP003, etc |

## 2. What is REDCap?

REDCap (Research Electronic Data Capture) is the secure web application that will be used for data capture for the SPACE-FLOT study. The SPACE-FLOT REDCap database is housed at PeterMac and has been built specifically to enable users to enter data efficiently and accurately to meet study objectives.

## 3. Accessing your REDCap account

**3.1 Logging in to REDCap**

All registered collaborators will receive an email providing access to the REDCap database for the SPACE-FLOT study.

*NB: if you have not received an email or do not have access please contact Kat Hall (SPACE-FLOT Study Coordinator) for assistance.*

*3.1.1 To log in to REDCap for the first time:*

☞ Click on the email link to login for the first time

☞ You will be prompted to change your password

☞ Follow the instructions to set up a new password

 *NB: Please keep this password secure and do not share with others.*

*3.1.2 To log in to REDCap all subsequent times:*

☞ *Navigate to https://redcap.petermac.org.au/ and enter username and password and click 'Log in'*

**REDCap®**

**Log In**

Please log in with your user name and password. If you are having trouble logging in, please contact Application Support.

| Username: | |
| Password: | |

Log In  Forgot your password?

☞ You will be directed through a two-step authentication pathway as per below
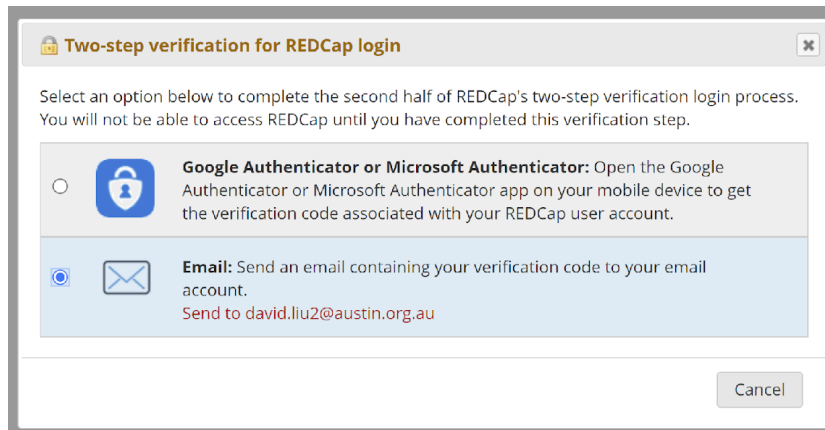
☞ Select the method you prefer to use e.g. Email, log into your registered institutional email account, wait for the automated email containing the verification code, copy and paste that code into the box below and press submit
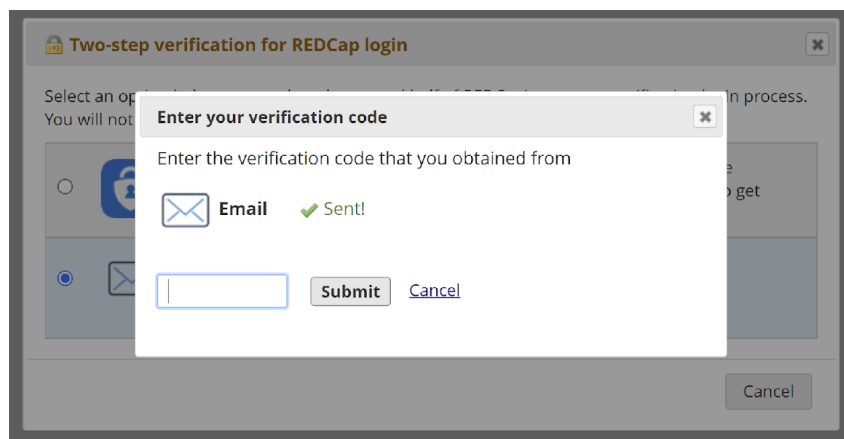


## 3.2 Navigating to the SPACE-FLOT REDCap Project

☞ After you have logged in you will be taken to this page
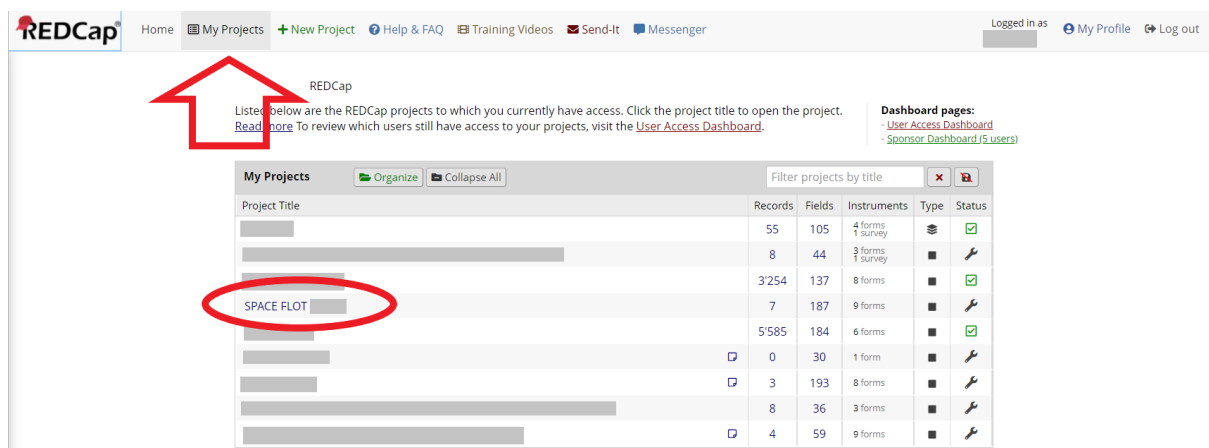


☞ Click on the project titled **"SPACE-FLOT"**

☞ This will take you to the **SPACE-FLOT REDCap Project Homepage**

## 4. Entering data for new cases

Every patient entered into the database will require ONE RECORD each and will have a unique REDCap identifying number. This number is automatically allocated to the record when you click **"Add/Edit Records".**

Data can be entered into REDCAP all at once or at different points in time.

### 4.1 Creating a new record

To begin entering data, you need to create a new record.

☞ Click **"Add/Edit Records"** under the **"Data Collection"** heading on the left-hand side of the **Project Homepage**
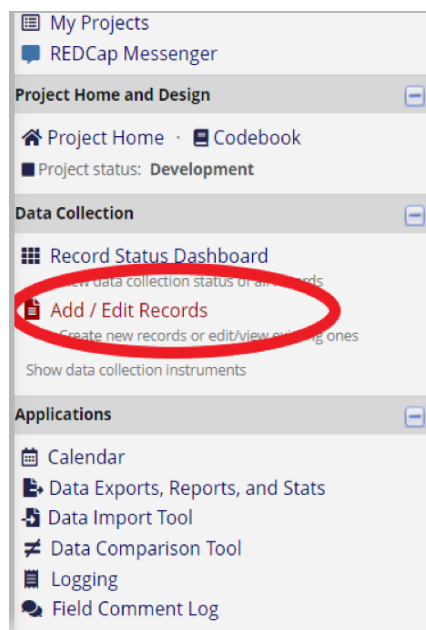


☞ Select the green **"+ Add new record"** button.
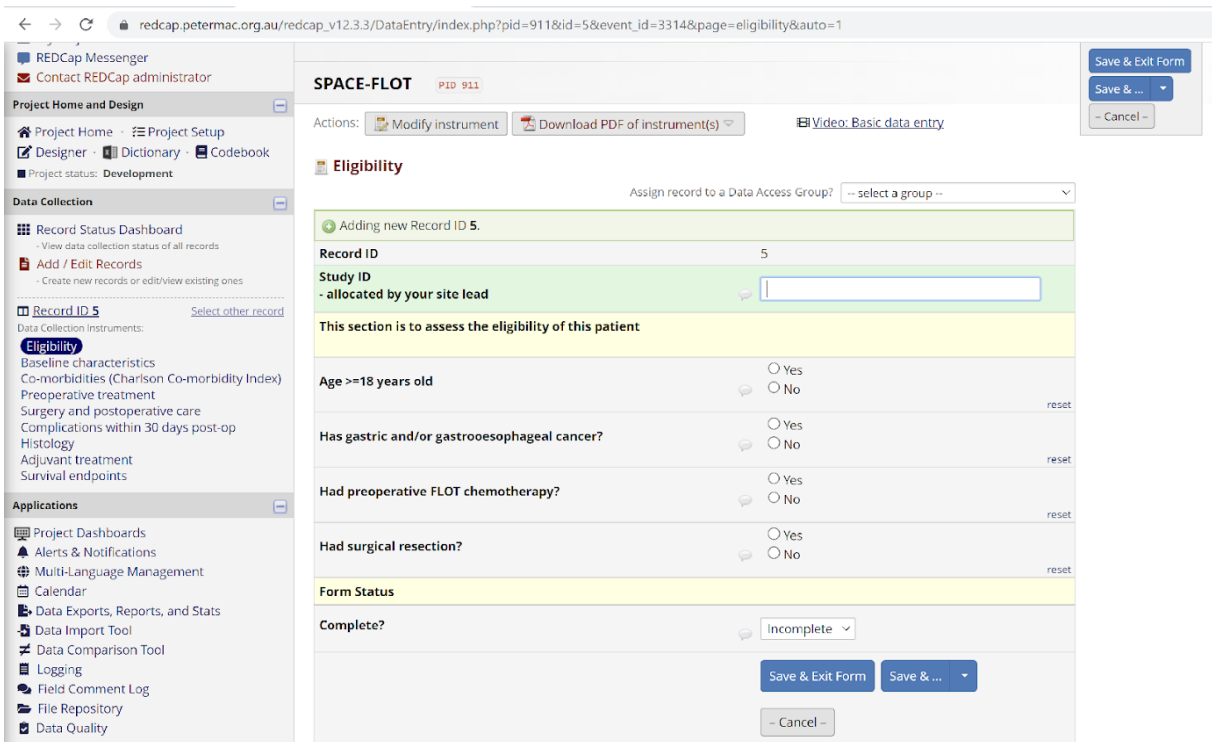
A REDCap study ID will be automatically generated and displayed as the ***Record ID***.
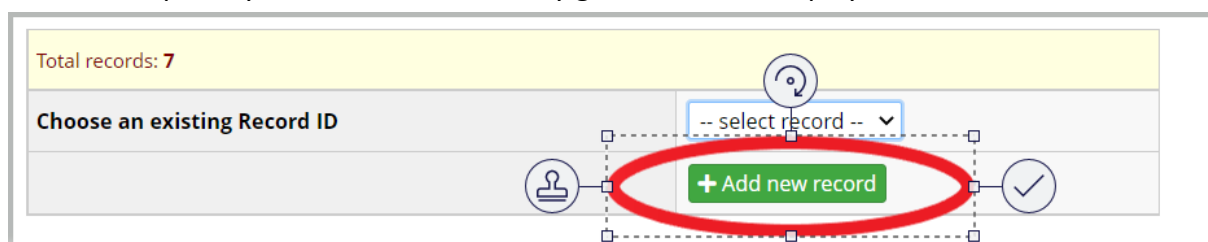
☞ This will take you to the list of data collection forms as below. Click on the radio button 'O' in the status column to begin entering data. Start at Eligibility and work your way through each data collection instrument for each patient



☞ Enter in study ID. This is a unique code for this patient for the purpose of this study. The study ID should be found in the Patient Identification Log



**Please note:** You cannot enter patient identifiers into REDCap.
Therefore, you must use a document titled "Patient Identification Log" to connect the patient's identifiers and the REDCap ID. This document should be captured on a secure, encrypted spreadsheet on a hospital, password protected computer.
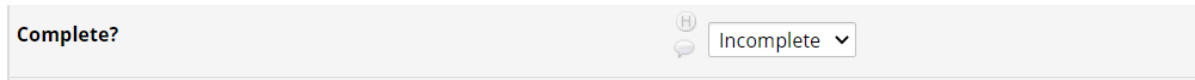
## 4.2 Entering data into records

Work your way through each question within each data collection instrument

If there are incomplete data fields in the data collection instrument, the drop down box at the bottom of the instrument should be left as '**Incomplete'** to indicate where missing data fields require entry in the future.



Once all data fields in the instrument are entered, verify this by clicking **"Complete"** in the drop-down box.
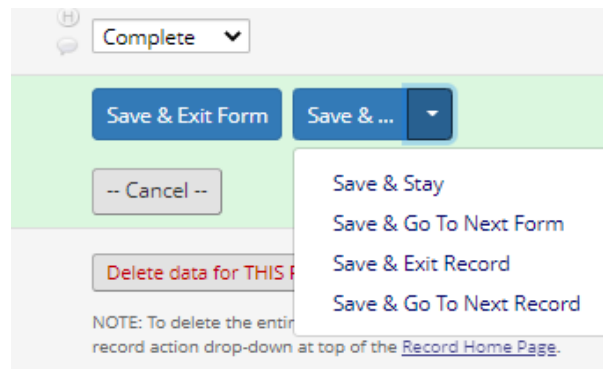


> At the end of data entry for each patient, all data collection instruments must be complete.
> *NB: Data entry can be completed at different points in time, you may return to complete data for each patient prior to REDCap being locked for data analysis*

### 4.2.1 Saving data

You may save the data on the form at any time by clicking the buttons at the bottom of each data collection form.



| Save & Stay | Saves the record as it is and remains on form |
|---|---|
| Save & Exit Form | Saves the record and returns the user to the **"Add/Edit Records"** homepage |
| Save and Go To Next Form | Saves the form and takes the user to the next form in that record |

| Save and Go to Next Record | Saves the form and takes the user to the <u>next record</u> |
|---|---|

If you save a form with incomplete data, you will be prompted that required fields are missing.  You may choose from the following three options:

| Okay | User is returned to the incomplete form |
|---|---|
| Ignore and leave record | User is returned to the **"Add/Edit Records"** homepage |
| Ignore and go to next form | User is taken to the <u>next form in the record</u> |

> Be sure to save your data entry at regular intervals as REDCap does <u>NOT</u> autosave.

When you return to the **"Record Home Page"** the radio button will identify which forms have been **completed**, which are still **unverified** (not all data has been entered) and which are **incomplete** using a traffic light coding system.
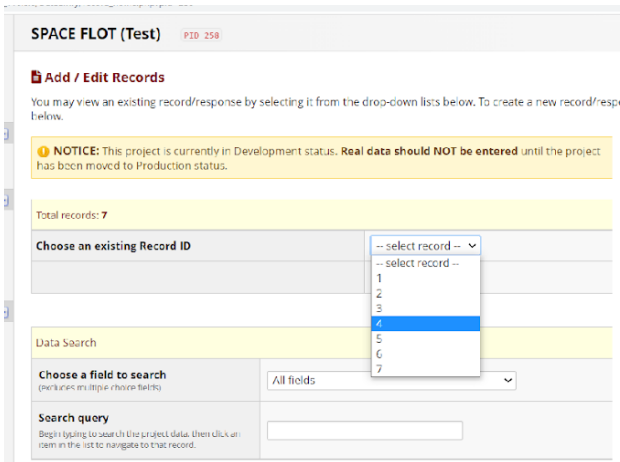
# 5. Entering data for pre-existing cases

You can access records at any time from the **"Add/Edit Records"** home page.

☞    Using your sites <u>Patient Identification Log</u>, determine the REDCap ID that corresponds with the patients UR

☞    You can then select from the drop-down menu the relevant **REDCap ID** and edit the relevant form



Record ID **4**

| Data Collection Instrument | Status |
|---|:---:|
| Eligibility | 🔴 |
| Baseline characteristics | 🟢 |
| Co-morbidities (Charlson Co-morbidity Index) | 🟢 |
| Preoperative treatment | 🔴 |
| Surgery and postoperative care | 🟢 |
| Complications within 30 days post-op | 🟢 |
| Histology | 🟢 |
| Adjuvant treatment | 🟢 |
| Survival endpoints | 🟢 |

# 6. Data Completeness

### 6.1 Marking a form as complete

Please complete <u>all</u> fields that appear on each **REDCap record**.

*NB: further information about key variables can be found in the SPACE-FLOT Protocol.*

When a record is **complete** (i.e., all possible fields have been filled in), you can mark the form as **"Complete"** by changing the form status field from **"Incomplete"** to **"Complete"**.

**This patient is eligible for this study. Please proceed with data entry.**

**Form Status**

Complete?                                              Complete ▼

Save & Exit Form    Save & ... ▼

> REDCap will allow you to mark a form as complete even if all data fields are not filled. Please ensure that all your data fields are complete before marking as '**complete**'

## 6.2 Identifying missing data

As you complete each of the forms for a patient, REDCap will identify which sections are incomplete 🔴 and which are complete 🟢.

### Record ID 3

| Data Collection Instrument | Status |
|---|---|
| Eligibility | 🔴 |
| Baseline characteristics | 🟢 |
| Co-morbidities (Charlson Co-morbidity Index) | 🟢 |
| Preoperative treatment | 🟢 |
| Surgery and postoperative care | 🟢 |
| Complications within 30 days post-op | 🟢 |
| Histology | 🟢 |
| Adjuvant treatment | 🟢 |
| Survival endpoints | 🟢 |

## 6.3 Locked data

When a record is **complete** (i.e. all forms are **complete** 🟢 in the data collection table for that record), the record may be '**locked**'. This indicates to the SPACE-FLOT Data Analysis Team that the data from that patient is final and accurate.

☞       To lock data, click '**Lock Record**' on the relevant **Data Collection** form.

# 7. FAQs

**What is the link to the REDCap database?**
https://redcap.hmri.org.au
Project link: https://redcap.petermac.org.au/

**How do I get a REDCap login and password?**
Please provide your full name, organisational email and study site to Kat Hall
(katheryn.hall@petermac.org ).

You will then be registered for the SPACE-FLOT PeterMac REDCap database and receive an email link to enable your access.

**Who do I contact if I am having trouble accessing or using REDCap?**
Please contact the SPACE-FLOT Study Coordinator, Kat Hall on katheryn.hall@petermac.org.

**Who do I contact if I have questions about data entry?**
There will be a WhatsApp group created to support real time data collection.

Should you have any question directly related to data entry whilst entering data please post on SPACE-FLOT WhatsApp group and we will respond as quickly as possible.