





WASHOUT – Patient project instructions

General 1

- Log in to REDCap (https://redcap.slms.ucl.ac.uk/)
 - Go to "My Projects" \rightarrow when the patient project opens, you will now see "WASHOUT (Data Entry)".



Figure 1. The Study Process

2 Phase 1: Study Registration

2.1 Phase 1: Official Site Registration

- Complete the official site registration form on REDCap (https://t.co/2uUDQQwIRn)
 - Note: The official site registration form is different from the pre-registration form and needs to be filled up in order to begin data collection
 - Please ensure the email address provided will be valid for the duration of the study in order to receive your certificates without delay and to receive important communications.

Lead collaborators can add new collaborators using the hospital registration form
 all collaborators will receive a REDCAP login to enter patient data.

You will be invited to start Phase 2: prospective patient data collection on REDCap

3 Phase 2: Prospective Patient Data Collection

- Get started on phase 2
 - Add incoming cases on REDCap Data Collection Form (<u>https://redcap.slms.ucl.ac.uk/redcap_v14.1.5/index.php?pid=6329</u>) under "Add/edit records"
 - Submit a minimum of 15 prospective cases per site for 1 collaborator and 1 supervising consultant
 - An additional 10 prospective cases are required for each additional collaborator

3.1. Identifying Consecutive, Eligible Cases - Phase 2: Prospective Patient Data Collection

- 3.1.1. Phase 2, Eligibility of "Prospective" cases
 - Should only include haematuria cases occurring after the start of the data collection period
 - You cannot go back to include cases that presented before the start of data collection for Phase 2
- Inclusion criteria:
 - Patients will be included consecutively if:
 - They are over 18 years of age

AND

- Admitted to a participating secondary care centre as an emergency with haematuria under the primary or joint care of the urology team.
- Exclusion criteria:

- Catheter-related urethral trauma (defined as haematuria immediately after insertion of a urethral catheter, without a preceding history of haematuria prior to this admission, and including traumatic catheter removal by patients).
- Urological trauma (abdominal/pelvic).
- Patients that are in hospital less than 24 hours.

4 Data entry periods

4.1 Once the patient project opens, you can submit data about haematuria cases at anytime through the period of Phase 2

• Prospective data entry will not "close" as you begin Phase 3; you can work on cases in both phases simultaneously until the stipulated deadline for the closure of Phase 2 data collection (after 12 months of recruitment)

4.2 Following the closure of Phase 2 data collection period, you will only be allowed to complete follow-up data on patients in Phase 2 until the end of the audit (3 months follow-up period following recruitment of last patient).

5 Using the REDCap patient database

• Login to **REDCap** \rightarrow Go to "My Projects"

5.1 Data entry to the Patient Project

- You should now see 1 project
 - WASHOUT Patient Project

5.2 Keeping a patient ID "key" at your site

• <u>No patient identifiable information should be entered or stored within the REDCap</u> <u>database</u>

- Patients will be allocated a unique audit ID number when you create a new record e.g. 4879-1
- You must keep an audit ID patient identity key (ID key) at your site, stored by the clinical care team
- This is essential since you will need it to:
 - Prevent duplicate data entry for the same patient
 - Identify the patient record to enter follow up data
- We recommend the ID key is stored in a secure file on your hospital computer system, or on paper in a locked drawer or cabinet in a clinical office where all collaborators can access it
- Please ensure this is preserved for the duration of the study to enable you to enter followup data at a later stage
- The ID key should never be shared with anybody outside of the clinical care team at your hospital
- The ID key should never be shared with the WASHOUT audit team

5.3 Adding a new record or editing data for existing records

5.3.1 Adding a new record

• Exclude data duplication:

• First – CHECK your site patient ID key to make sure the patient you are about to start a new record for does not already have a record in the database (somebody else may have already entered this patient)

• Start adding your record:

• Once you have confirmed the patient does not already exist in the database, you can create a new record by clicking on "Add/ Edit Records" and then clicking the green button:

Data Collection — BURST pilot				
 Record Status Dashboard View data collection status of all records 				
Add / Edit Records - Create new records or edit/view existing ones				
Show data collection instruments				
Total records: 28 / In group: 13				
Choose an existing Record ID	select record 🗙			
	+ Add new record			

5.3.2 Editing, checking or reviewing existing records

- Please click on "**RECORD STATUS DASHBOARD**" on the left sidebar under "data collection". It should show you a snapshot of all patients entered from your site.
- The table will show you which forms are complete or incomplete.
 - **Green circle =** complete.
 - **Red circle** = incomplete.
 - Grey circle = not filled.
- To review or edit a patient record, either click on the patient ID to the left, or click on the circle for the individual form.
- The PDF of the data collection forms are available to check what information is required in advance. You can also save and return to the form later if you have missing data.

Displaying: Instrument status only <u>Lock status only</u> <u>All status types</u>					
Record ID	Form 1: Admission details (ideally completed on admission)	Form 2: Management and outcomes (ideally completed on discharge)	Form 3: Data quality checking form (completed directly after Form 2)	Form 4: Follow-up outcomes (to be completed at 90 days)	
<u>10603-1</u>		۲			
<u>10603-2</u>	۲	۲			
<u>10603-3</u>	۲	۲			
<u>10603-4</u>	۲	۲	\bigcirc		
10603-5		۲			

5.3.3 Searching records

Depending on the number of entries, it may be unwieldy to search for records manually.

- Should you have your patient ID → press "CTRL + F" (WINDOWS) or "COMMAND + F" (MAC) and type the patient ID in the pop-up box.
- If you don't have your patient ID, please contact your lead collaborator to locate the patient ID which should be securely stored at your site.
- In exceptional circumstances where the patient ID is inaccessible or lost, you can attempt to identify the patient from their medical history and/or characteristics.
 - Go to "Add / Edit Records" on the left sidebar under "data collection" → use "data search" to search any field in the database.

		Click here to select field e.g. age	
Data Search			
Choose a field to search (excludes multiple choice fields)	All fields	~	
Search query			
Begin typing to search the project data, then click an item in the list to navigate to that record.		×	
		Type search term	

5.4 Adding data

Record Home Page

5.4.1 Data collection forms (are called "instruments" in REDCAP)

• Once you have finished your data entry and saved it, you will be able to view this page listing all the forms that require completion (if applicable).

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.		Legend for status icons: Incomplete Incomplete (no data saved) [Unverified Complete		
Record ID 10603-6				
Data Collection Instrument	Status			
Form 1: Admission details (ideally completed on admission)	۲			
Form 2: Management and outcomes (ideally completed on discharge)			
Form 3: Data quality checking form (completed directly after Form 2)				
Form 4: Follow-up outcomes (to be completed at 90 days)				

 Please immediately note the patient record ID on your study ID key with your patient's hospital number → this is for your reference and will assist you going forwards.

6. Summary

• There are a total of **five forms** to complete.

- **Form 1** \rightarrow admission details.
 - Ideally completed on admission.
- Form $2 \rightarrow$ management and outcomes.
 - Ideally completed on discharge.
- **Form 3** \rightarrow data quality checking form.
 - For a record to be verified, both a manual entry and automatic calculation of the length of stay is required. You will be asked to return and fill out form 2 if these conditions have not been met.
- **Form 4** \rightarrow follow-up outcomes.
 - This form will open 90 days after data entry for a patient.
- Form $5 \rightarrow$ data quality checking form (follow-up)
 - For a record follow-up data to be verified, Form 5 needs to be unlocked and viewed to verify record.
- We appreciate there are many components to the REDCAP form. As such, we have
 inserted detailed guidance throughout the forms to assist you with data entry. Should you
 require further assistance, or if anything is not clear at all, please get in touch with us by
 emailing washout@bursturology.com.