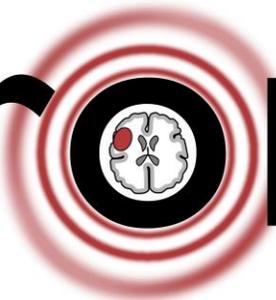


cromis-2

The logo for 'cromis-2' features the word 'cromis-2' in a bold, black, sans-serif font. The letter 'o' is replaced by a graphic consisting of a stylized brain with a red dot on the left side, surrounded by three concentric red circles with a white border, creating a ripple effect.

Clinical Relevance Of Microbleeds In Stroke

A GUIDE TO COMPLETING THE
ELECTRONIC CASE REPORT FORMS
(ECRF)

VERSION 1.0 APRIL 2012

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INTRODUCTION

The CROMIS-2 study now has an online application for collecting and managing data on patients recruited the study.

It has been created for the CROMIS-2 study by a company called Sealed Envelope Ltd.

This user guide is intended for users with researcher/PI level privileges to the application and describes the features available to users with these privileges.

This hand book is divided into **Part I and Part II**.

PART 1: CROMIS-2 ELECTRONIC DATA SYSTEM

ACCESSING THE ELECTRONIC DATA SYSTEM

Access to the application is via a URL specific to the CROMIS-2 study – <https://www.ucl.ac.uk/cromis-2>. This URL will be contained in the automated email that should have been sent out to you when you needed to create a new user account.

Click on the 'secure log in button'. You will be requested to authenticate yourself before access is granted to the system by providing your email address, password and PIN number (see Figure 1).

Figure 1: Log in screen

If you do not have an account, or provides an incorrect password or PIN you will not be allowed access.

New users can request an account by asking an existing administrator user to create one for them. The administrator account has been created for the CROMIS-2 Study Co-ordinator.

The Study Co-ordinator can create new accounts as required. When a user has logged in their name and unique user ID number is always shown at the top of every page in the navigation bar.

Once you have finished using the database application it is good practice to log out. This is particularly important if the user is not using his or her own computer.

To log out click on the 'Logout' link in the navigation bar at the top of the page.

Note that to comply with good clinical practice (GCP) it is very important that users do not share accounts or allow others to access their accounts, even temporarily.

Forgotten passwords

If you forget your password or log in details they should contact the CROMIS-2 study co-ordinator. Administrators can reset a user's password and PIN in the 'User accounts' section. This sends out a new password and PIN by email to the account holder.

Note that there is no way to see a user's current password and PIN - they are stored in an encrypted format that not even Sealed Envelope staff can decrypt. Requests for password resets made by investigators to Sealed Envelope will be referred to the study co-ordinator since Sealed Envelope has no way of authenticating the validity of such requests.

Changing password or PIN

Using the 'My account' link shown in the top navigation bar, you can change your own email address, password and/or PIN. To change a password or PIN it is necessary to enter your existing password. New passwords must be at least 6 characters long. New PINs must be 4 digit numbers. Passwords expire after 6 months, after which time a user is forced to change their password or PIN. Users with expired passwords have no access to the system except for the change password screen.

Auto time-out

After a set period of inactivity (20 minutes) you will be automatically logged out of the system.

Creating your account

The CROMIS-2 Study Co-ordinator can create new user accounts. To create an account the user's real name and email address must be supplied (Figure 8). Once the account is created an automatically generated email is sent to the email address supplied containing the randomly generated password and PIN necessary to access the account.

An example of the generated email is:

From: automated@sealedenvelope.com

Subject: Confidential: new account details

Date: 15 July 2009 11:10:17 BDT

To: joe@trialsite.org

Dear Joe Bloggs,

An account with investigator privileges has been created for you to access CROMIS-2 (<https://www.sealedenvelope.com/CROMIS-2/>).

Email: jbloggs@gmail.com

Password: LkFXkaju

PIN: 9996

Note, this message was auto-generated on Tue 21 Feb 2012 11:10 Europe/London (GMT +0100) and was sent from an email address that does not accept replies.

After you have logged in ideally you should change your password and PIN number and delete this email. If you have any difficulties please contact Clare Shakeshaft (c.shakeshaft@ucl.ac.uk).

Editing accounts

Existing accounts may be edited the CROMIS-2 Study Co-ordinator, to update the account email address, name and status (active or suspended). The user's name should only be changed to correct spelling mistakes.

Existing user accounts should not be re-allocated to new users. User accounts that are no longer in use should be suspended and new accounts created for new users.

Deleting accounts

There is no facility for deleting accounts. This is to preserve the audit trail and history of who performed which actions. To remove the ability for an account to access the system the account should be edited and the status set to suspended.

Logging in

After you have successfully logged in, you will be presented with a welcome page with a short description of the trial and their user account role (Figure 2). This screen can be returned to at any time by clicking on 'Home' in the navigation bar at the top of the page.

Trials

[CROMIS-2 Study I](#)

Microbleeds and genetic risk factors to predict the risk of intracranial haemorrhage in patients treated with anticoagulation following cardioembolic stroke due to atrial fibrillation.

Your role in this trial is: Administrator.

[User accounts](#)

You receive notifications for this trial.

Trial ID 1

[CROMIS-2 Study II](#)

Observational and genetics study of intracerebral haemorrhage.

Your role in this trial is: Administrator.

[User accounts](#)

You receive notifications for this trial.

Trial ID 2

Thu, 23 Feb 2012 13:3

Figure 2: Example home screen after logging in. Choose appropriate study, Study I (AF) or study II (ICH)

Click on the relevant study, and you will be presented with the study log and the ability to add patients, see overdue forms, view queries and reports. Each of these functions will be discussed in the next sections.

Home | Logout Clare Shakeshaft (ID 4)

CROMIS-2
Study I

Patients
Overdue forms
Queries

cromis-2
Clinical Relevance Of Microbleeds In Stroke

Study I: CROMIS-2 (AF)
Prospective cohort study of patients anticoagulated after cardioembolic stroke.

Wed, 28 Mar 2012

Figure 3: Example study specific screen after selecting study I (AF) or study II (ICH) on the home screen

PATIENTS

Viewing existing patient data

Patient records can be viewed by clicking on the 'Patients' link in the left-hand sidebar. This shows a list of all patients entered into the study to date at your hospital.

New patients

New patients may be added to the list by clicking on the 'add patient' link near the top of the page.



Figure 4: Screen showing how to add a new patient

This opens the study entry form. After you have entered the information and ensured data accuracy, select the 'Save form' option.

Study entry

Enter the patient identifier and the date of entry to the study.

Study entry

1. Patient identifier

2. Date of study entry

 
dd/mm/yyyy

Notes

Figure 5: A new study entry form

Allocating Study Numbers

The patient ID will be obtained at the time of enrollment. The first part of the ID (##) represents the Site ID. The second part of the ID (###) represents the unique patient number. The Centre ID and patient ID will not need to be entered at each visit and will populate automatically at the top of the screen after initial entry at the Baseline form.

The system will alert you to any missing patient information prior to moving to the next form. The completed form will be saved and you can 'view' this form at any point. The Patient individual patient record is where you will see all saved patient forms, see Figure 6.

You can return to a patient home page by clicking 'return to patient' or you can continue to the next section of the form. Alternatively, you can jump to a specific form using the drop down list.



Figure 6: Screen showing how to move to new forms or return to patient home screen.

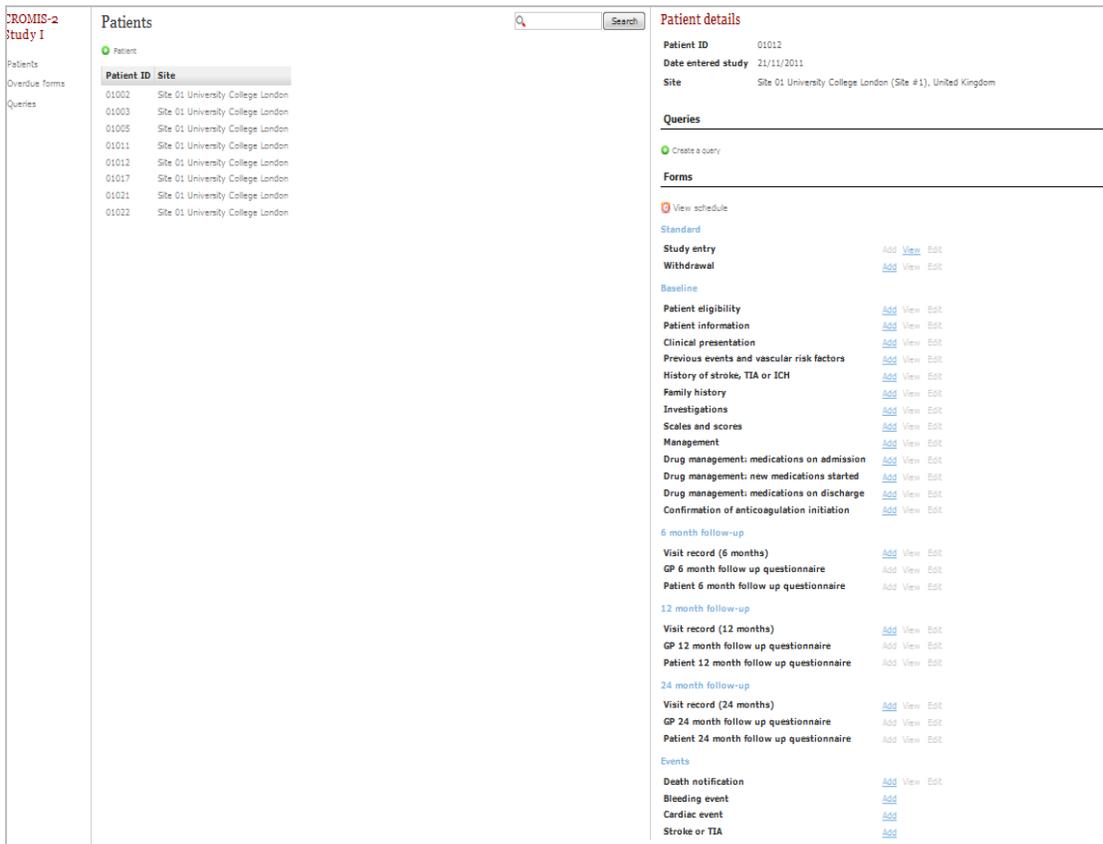


Figure 7: Viewing an individual patient record

Clicking on a patient in the list shows patient details from the study entry form, any queries and provides links to add the baseline CRF, and positive event forms, and follow up forms for that patient.

The search box searches through patient IDs and returns a list of patients that match the terms entered. Note that CRF data is not searched

Overdue forms

Overdue CRFs for all patients may be viewed by clicking the 'Overdue CRFs' link in the left hand side bar.

View Schedule

Patient ID 01030 | Date entered study 06/03/2012 | Site 01 University College London (Site #1), United Kingdom

[Return to patient](#)

Schedule

Standard

Form	Due	
Study entry	6 Mar 12	Done
Withdrawal	at any time	

Baseline

Form	Due	
Patient eligibility	6 Mar 12	Overdue
Patient information	6 Mar 12	Overdue
Clinical presentation	6 Mar 12	Overdue
Previous events and vascular risk factors	6 Mar 12	Overdue
History of stroke, TIA or ICH	6 Mar 12	Overdue
Family history	6 Mar 12	Overdue
Investigations	6 Mar 12	Overdue
Scales and scores	6 Mar 12	Overdue
Management	6 Mar 12	Overdue
Drug management: medications on admission	6 Mar 12	Overdue
Drug management: new medications started	6 Mar 12	Overdue
Drug management: medications on discharge	6 Mar 12	Overdue
Confirmation of anticoagulation initiation	6 Mar 12	Overdue

6 month follow-up

Form	Due	
Visit record (6 months)	6 Sep 12	

12 month follow-up

Form	Due	
Visit record (12 months)	6 Mar 13	

Figure 8: Showing schedule of patient

Data entry of forms

CRFs, withdrawal forms, follow up form, event forms and death notification forms can be completed by clicking on the 'Add' link shown on the patient details home screen next to the name of the CRF.

6 month follow-up		
Visit record (6 months)	Add	View Edit
GP 6 month follow up questionnaire	Add	View Edit
Patient 6 month follow up questionnaire	Add	View Edit
12 month follow-up		
Visit record (12 months)	Add	View Edit
GP 12 month follow up questionnaire	Add	View Edit
Patient 12 month follow up questionnaire	Add	View Edit
24 month follow-up		
Visit record (24 months)	Add	View Edit
GP 24 month follow up questionnaire	Add	View Edit
Patient 24 month follow up questionnaire	Add	View Edit
Events		
Death notification	Add	View Edit
Bleeding event	Add	
Cardiac event	Add	
Stroke or TIA	Add	

6 month follow-up		
Visit record (6 months)	Add	View Edit
GP 6 month follow up questionnaire	Add	View Edit
Patient 6 month follow up questionnaire	Add	View Edit
Events		
Death notification	Add	View Edit
Bleeding event	Add	
Cardiac event	Add	
Stroke or TIA	Add	

Figure 9: Follow up forms and event forms in patient for study I and study II

At the top of every form is a banner reminding the user of which patient they are entering data on. Date fields can be completed manually or by using the date-picker that appears when a user clicks on the calendar icon.

Tip: When entering dates or times manually, just type the numbers – the / or : will be filled in automatically.

Validation

Validation (e.g. range checking) is carried out on the form to reduce errors. There are two types of error messages – those in the form of popup messages and those displayed in red on the form. The popup message alerts may warn the user of a value that may be incorrect (such as a high blood pressure) or give some other message.

CROMIS-2 Study I

Patients
Overdue forms
Queries

Patient ID 01022 | Date entered study 23/01/2012 | 3

Return to patient

Clinical presentation

Clinical presentation

1. History collected at

Stroke/TIA clinic

Stroke Unit

Other

This field is required.

Justification for overriding validation "This field is required.":

2. If other, please specify

Figure 10: Red error message

The user must click 'OK' to dismiss the alert before proceeding. Red error messages require either a change to the value entered or providing a justification for overriding the validation check before proceeding (Figure 10).

A comprehensive guide to completing study I (AF) and Study II (ICH) baseline forms, positive event forms, death notification forms, follow up forms and withdrawal forms can be found in Part II of this guide.

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History of stroke, TIA or ICH

History of previous ischaemic stroke, transient ischaemic attack (TIA) or intracerebral haemorrhage (ICH)

History

1. Previous ischaemic stroke
No
2. Total number of all previous ischaemic stroke events
-
Number (up to 2 digits)
3. Please record date of most recent previous ischaemic stroke event
-
dd/mm/yyyy
4. Date of the first ever ischaemic stroke
-
dd/mm/yyyy
5. Previous transient ischaemic attack (TIAs)
No
6. Total number of all previous transient ischaemic attack (TIA) events
-
Number (up to 2 digits)
7. Please record date of most recent previous TIA event
-
dd/mm/yyyy
8. Date of the first ever TIA
-
dd/mm/yyyy
9. Previous intracerebral haemorrhage (ICH)
No
10. Total number of all previous ICH events
-
Number (up to 2 digits)
11. Please record date of most recent previous ICH event
-
dd/mm/yyyy
12. Date of the first ever ICH
-
dd/mm/yyyy

Figure 11: Review page presented after saving form

Some fields are always required – these are displayed in bold text – whilst others may become required or not applicable depending on the answers to previous questions. Other fields are optional and may be left blank if desired.

Once the form has been completed without errors the 'Save form' button will present the user with a review page (Figure 11). If there are errors the user may return to the previous page to make changes. Once successfully completed the form is saved to the database.

If, at any time before this, the user navigates away from the page (e.g. they click on the 'return to patient' link), the data entered will be lost. The user is warned of this by a pop-up message that appears when navigating away from the form.

QUERIES

Queries are intended to be used by administrators (Co-ordinating Centre) to raise questions about the CRF data for investigators (PI/Research teams at sites) to answer and for investigators to notify administrators of any issues they are aware of. Queries can be linked generally to a patient, or more specifically to a particular CRF for a patient. Queries may only be closed by administrator users. Investigators can create new queries and add messages to existing queries.

Opening queries

A query can be opened either on the patient details panel or when viewing a CRF, by clicking on the 'Create a query' link (Figure 12). The query must be given a title and an initial message. To link the query to a specific CRF, choose the appropriate form from the related CRF drop-down control (Figure 13). Once it has been created, the query will be shown on the patient details panel and CRF specific queries will also be shown when viewing the CRF. In addition, if a CRF has an open query attached, a yellow warning symbol appears next to the form name in the patient details panel.

Note that creating a query or re-opening a closed query linked to a CRF will cause the CRF to be marked as not validated.

Patient details

Patient ID	01002
Date entered study	10/10/2011
Site	Site 01 University College London (Site #1), United Ki

Queries

[+ Create a query](#)

Forms

[View schedule](#)

Figure 12: How to create a query

Adding messages

Messages may be added to queries by investigators (sites) or administrators (Co-ordinating centre), forming a conversation thread (Figure 15). Administrators can close a query when the issue has been resolved. Administrators may also re-open a closed query by setting the action to 'Reopen' when adding a new message to it.

When editing a query (Figure 15), printing the web-page will display an extra box that asks the investigator to write their response, with signature and date (). This may be useful for the site's own records or workflow.

[Return to patient](#)

Create a query

Related form
Standard Study entry ▼

Related question
Choose... ▼

Title

Message

[Create query](#)

Figure 13: Entering query title and message

Email notifications

When a query is created, or a message added to an existing query, an email notification is sent out to all administrators, and all investigators at the same site as the patient the query relates to. The format of the email is:

From: Sealed Envelope <automated@sealedenvelope.com>

Subject: [CROMIS-2] Query updated

Date: Wed, 28 March 2012 15:43:22 +0100

To: joe@trialsite.org,admin@trialcentre.org

A query "Incorrect date?" has just been created by Clare Shakeshaft (ID 4).

You can view the query here:

<https://www.sealedenvelope.com/redpill/cromis2study1/query/view/1>

Query ID 2: Incorrect date of entry?  [Edit]

Current status: Open
This query relates to the [Standard Study entry](#) form
[View patient](#)

Messages

Action: Open, Clare Shakeshaft (ID 4) on 28 Mar 2012 at 04:13:56 PM
Re: 2. Date of study entry is listed as 2009? should this be 2012?

Wed, 28 Mar 2012 16:14:15 +0100 | 1.0.1

Figure 14: Response box shown when editing a query. User must click on 'edit'

Listing queries

A list of queries grouped by site is displayed by clicking on the 'Queries' link in the sidebar (Figure 15). The conversation thread for a query can be viewed by clicking on the query in the list. This view also displays links for editing the query or viewing the related patient or CRF.

Query ID 2: Incorrect date of entry?

Current status: Open

Clare Shakeshaft (ID 4) on 28 Mar 2012 at 04:13:56 PM Action: Open

Re: 2. Date of study entry
is listed as 2009? should this be 2012?

Message

Add message

This query relates to the following form:

Study entry

Enter the patient identifier and the date of entry to the study.

Study entry

1. Patient identifier
01003
2. Date of study entry
14/03/2012
dd/mm/yyyy

Figure 15: Adding a message to an open query linked to Form 1

Home | Logout Clare Shakeshaft (ID 4)

**CROMIS-2
Study I**

Patients

Overdue forms

Queries

Queries

ID	Title	Status
Site 01 University College London		
1	Incorrect date?	Open
2	Incorrect date of entry?	Open

Queries

ID	Title	Status
Site 01 University College London		
1	Incorrect date?	Open

Query ID 1: Incorrect date? [Edit]

Current status: Open
 This query relates to the [Standard Study entry](#) form
[View patient](#)

Messages

Action: Open, Clare Shakeshaft (ID 4) on 28 Mar 2012 at 04:05:12 PM
 Re: 2. Date of study entry

Wed, 28 Mar 2012 16:07:08 +0100 | 1.0.

Figure 16: Viewing the details of a query

PART II: USER MANUAL

Part II of this handbook provides a guide for completing the electronic Case Report Forms (eCRFs) for both Study I (Atrial fibrillation-AF) and Study II (Intracerebral haemorrhage-ICH).

In addition, for the Scales and Scores to be collected as part of the eCRFs, this guide is provided for their administration and calculation).

STUDY ENTRY FORM

Enter the patient identifier and the date of entry to the study. The site should be automatically entered from the drop down box, applicable to your log in.

The patient identifier is the study number assigned to the patient, with the Enter the study number assigned to the patient, using a 5 digit format with the first two numbers as your allocated site number.

The last 3 numbers will be the next available number working upwards from 001. A site specific study number allocation form is provided to keep track of these figures. 'Patient Identifier' is a required field and must be entered to save the Study Entry form.

Entry the date the patient was recruited to the study. "Date of study entry" is a required field and must be entered to save the Study Entry form.

Study entry

Enter the patient identifier and the date of entry to the study.

Study entry

1. Patient identifier
01001

2. Date of study entry
29/03/2012 
dd/mm/yyyy

Notes

Save form

Figure 17: Study entry form

PATIENT ELIGIBILITY

This form must be completed to ensure all inclusion and exclusion criteria are met, and the patient is eligible to participate in the study. These criteria are explained in detail in the CROMIS-2 Researcher’s Handbook. All data must be entered in order to successfully save the eligibility form.

Inclusion Criteria

If any of the inclusion criteria listed above are checked “No”, the patient is NOT eligible for the study. A warning message will appear on the screen if any exclusion are checked ‘no’ (Figure 16).

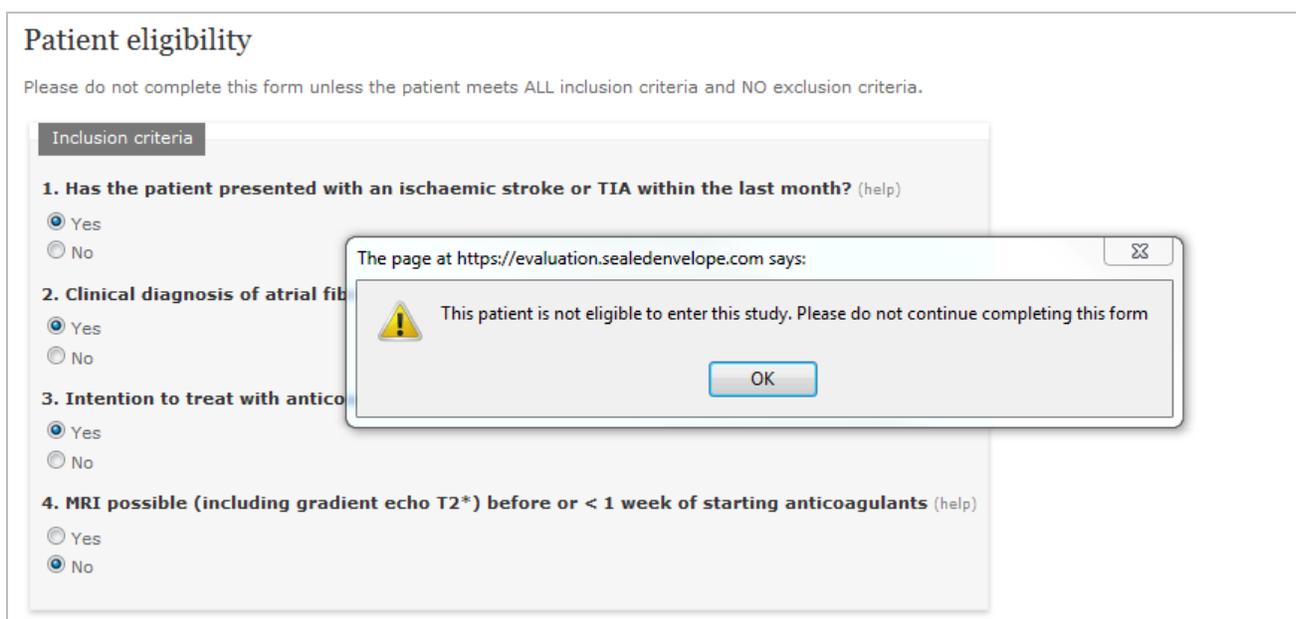


Figure 16: Example of Study I (AF) inclusion criteria warning message

Note: The only inclusion criterion for Study II (ICH) is that the patient must present with spontaneous ICH confirmed on neuroimaging (CT or MRI).

Patients with ICH secondary to an underlying cause (e.g. trauma, tumour etc.) are excluded from this study, as well as patients with isolated intraventricular or subarachnoid haemorrhage, and haemorrhagic transformation of an infarct.

Exclusion Criteria

If any of the exclusion criteria listed above is checked “Yes”, the patient is NOT eligible for the study.

The screenshot displays two sections of an eCRF form. The first section, titled "Exclusion criteria: MRI contradictions", contains questions 5 through 11. Each question has two radio button options: "Yes" and "No". In all cases, the "No" option is selected. The second section, titled "Exclusion criteria: Clinical contra-indications", contains questions 12 through 14. Question 12 has "Yes" and "No" options, with "No" selected. Question 13 has "Yes" and "No" options, with "Yes" selected. Question 14 has "Yes" and "No" options, with "No" selected. A warning dialog box is overlaid on the form, containing a yellow warning icon, the text "The page at https://evaluation.sealedenvelope.com says:", and a message: "This patient is not eligible to enter this study. Please do not continue completing this form". An "OK" button is located at the bottom of the dialog box.

Figure 17: Example of Study II (ICH) exclusion criteria warning message

Study II (ICH) Question 16. The Patient Eligibility section of the eCRF (shown below), aims to identify patients taking oral anticoagulation at the time of the ICH – but please note that this is **not** either an inclusion or exclusion criterion (see Figure 18).

- Relative not available
- **Study I: Patients with presumed ICH**
 - ICH due to secondary cause (e.g. tumour, AVM)
 - Not ICH
 - Relative not available

PATIENT INFORMATION

Please complete this section to provide basic demographic information on the patient, and to confirm that consent, either patient or consultee has been obtained, and the date consent was obtained.

Patient information

Patient information

- Sex**
 - Male
 - Female
- Ethnicity**
Black or Black British (Any other black background) ▼
- Hand preference**
 - Right
 - Left
 - Unknown
- Has written informed consent from patient been obtained?** (help)
 - Yes
 - No
- Date consent from patient obtained**

dd/mm/yyyy
- Has written informed consent from consultee been obtained?** (help)
Yes ▼
- Date consent from consultee obtained**

dd/mm/yyyy
- Consent to inform GP obtained?** (help)
 - Yes
 - No
- Date baseline data collected** (help)

dd/mm/yyyy
- Name of person completing this form**
- Position**
Research Nurse/ Research Practitioner ▼

Figure 19: Patient Information form

IMPORTANT NOTE: If consultee consent has been obtained, question 4 ‘Has written informed consent from patient been obtained?’ must be no. Instead, question 6. ‘Has written informed consent consultee been obtained?’ must be yes, and date entered accordingly.

4. Has written informed consent from patient been obtained? (help)

Yes
 No

5. Date consent from patient obtained



dd/mm/yyyy

6. Has written informed consent from consultee been obtained? (help)

Yes ▼

7. Date consent from consultee obtained

11/11/2011 

dd/mm/yyyy

Figure 20: Showing consent marked as ‘no’, instead consultee consent has been obtained and marked yes, with date inserted accordingly

Date baseline data collected: please use date completing the patient contact details.

CLINICAL PRESENTATION

Please complete this information to provide basic details of the current event.

Clinical presentation

Clinical presentation

1. History collected at

Stroke/TIA clinic

Stroke Unit

Other

2. If other, please specify

Current stroke history

3. Date of stroke/TIA (onset of symptoms)

31/10/2011 

dd/mm/yyyy

4. Is this the patient's first-ever TIA/stroke?

Yes

No

Unknown

Figure 21: Study I (AF) Clinical Presentation form

IMPORTANT NOTE: Date of stroke – enter date of stroke onset. If this is unknown, please enter date patient was admitted to hospital with this event.

Clinical presentation

Current ICH history

1. Date of ICH (onset of symptoms)
28/03/2012 
dd/mm/yyyy

2. First ever symptomatic ICH

Yes
 No
 Unknown

Symptoms at onset

3. Headache

Yes
 No
 Unknown

Symptoms at onset - weakness

4. Face weakness

Yes
 No
 Unknown

5. If yes, right or left?
Right ▼

Figure 22: Study II (ICH) Clinical Presentation form

PREVIOUS EVENTS AND VASCULAR RISK AND VASCULAR RISK FACTORS

Patient ID 01030 | Date entered study 06/03/2012 | Site 01 University College London (Site #1), United Kingdom

[Return to patient](#)

Previous events and vascular risk factors

Past medical history

- Hypertension (on anti-hypertensive treatment pre-event or 140/90 persisting >7 days after stroke or on two occasions before the stroke)**
 Yes
 No
 Unknown
- If yes, please specify year of diagnosis
2009
year. Number (up to 4 digits)
- Hypercholesterolemia (on treatment pre-stroke or fasting cholesterol total >5.2 mmol/L after stroke)**
 Yes
 No
 Unknown
- Diabetes type I/II (pre-event diagnosis or ≥ 2 random ≥ 11.1 mmol/L or ≥ 1 fasting ≥ 7 mmol/L after the event)**
 Yes
 No
 Unknown
- Smoking status**
Ex-smoker
- If current or ex smoker, number of cigarettes per day
20
Number (up to 5 digits)
- If ex smoker, year stopped smoking
2008
year. Number (up to 4 digits)
- Alcohol consumption**
Current
- If current drinker, how many units a week?
5
units. Number (up to 2 digits)
- If current drinker, type of alcohol the patient generally consumes the most (in units)
Spirits

Figure 23: Previous events form

HISTORY OF STROKE/TIA OR ICH

The “Past Medical History” section is followed by a brief section regarding the previous history of ischaemic stroke, transient ischaemic attack (TIA) or intracerebral haemorrhage (ICH), which is relatively straight forward to be completed (see below).

History of stroke, TIA or ICH

History of previous ischaemic stroke, transient ischaemic attack (TIA) or intracerebral haemorrhage (ICH)

History

1. Previous ischaemic stroke

Yes
 No
 Unknown

2. Total number of all previous ischaemic stroke events

Number (up to 2 digits)

3. Please record date of most recent previous ischaemic stroke event

dd/mm/yyyy

4. Date of the first ever ischaemic stroke

dd/mm/yyyy

5. Previous transient ischaemic attack (TIAs)

Yes
 No
 Unknown

6. Total number of all previous transient ischaemic attack (TIA) events

Number (up to 2 digits)

7. Please record date of most recent previous TIA event

dd/mm/yyyy

8. Date of the first ever TIA

dd/mm/yyyy

9. Previous intracerebral haemorrhage (ICH)

Yes
 No
 Unknown

10. Total number of all previous ICH events

Figure 24: History of stroke, TIA or ICH form

IMPORTANT NOTE: This section should not be confused with the next questionnaire (see next page), which is about the history of transient neurological episodes *other than* transient ischaemic attacks (TIAs) which may have occurred prior to the ICH.

Research suggests that such transient focal neurological episodes, with symptoms that are different to those of typical TIAs, can precede ICH in some patients. Most commonly, these attacks are described as paraesthesia (“pins and needles”). By contrast, TIAs generally cause a loss of neurological function, for example focal weakness or loss of sensation.

To elicit a possible history of these episode please ask both the patient and any relative/next of kin, and also check the medical notes.

The screenshot shows a questionnaire section titled "History of transient focal neurological episodes". Below the title is a sub-header "History of transient focal neurological episodes" in a grey box. The text below reads: "Research suggests that transient focal neurological episodes can precede ICH in some patients. Often these attacks are described as paraesthesias ('pins and needles') that move from one part of the body to another. The questions below are important to understand more about these attacks." The first question is "1. Can the participant (or reliable informant, e.g. a relative or close friend) provide a reliable history?" with radio buttons for "Yes" (selected) and "No". The second question is "2. Before the patient had an ICH, were there any attacks of the following: Paraesthesia, focal weakness, speech disturbance, limb shaking or jerking, visual disturbances or headaches?" with a dropdown menu showing "Yes". Below this is another sub-header "Paraesthesias" in a grey box. The third question is "3. Episodes of focal paraesthesias (pins and needles, tingling affecting part of the face or body)" with a dropdown menu showing "Yes". The fourth question is "4. Face paraesthesias" with a dropdown menu showing "Left only".

Figure 25: History of transient focal neurological episodes

A detailed description of these attacks will be very useful when available, and can be entered in Question 67 (see Figure 26)

The screenshot shows a questionnaire section titled "Summary" in a grey box. Below the title is question 67: "67. Please provide a description of the episodes in as much detail as possible (help)". Below the question is a text input field containing the following text: "Numbness and a tingling sensation around the corner of the mouth on the right (she is not sure whether the tongue is also involved); after 2-3 minutes the abnormal sensations spread to the right hand, over 1-2 minutes, without any obvious weakness."

Figure 26: Description of episodes

SCALES AND SCORES (APPLIES FOR BOTH STUDIES)

The scales and scores should be completed during patient's admission.

Scales and scores to be completed include:

1. **IQ-CODE (short version):** to be given to the patient's relative/ carers / other informant to complete
2. **MoCA (Montreal Cognitive Assessment):** to be administered to the patient by a research practitioner or other appropriate member of the research team
3. **EQ-5D-5L:** to be given to the patient to complete
4. **Modified Rankin Scale:** to be completed by the researcher completing the CRF

Please find below detailed instructions of how to complete each of these scales and scores. These scores should be entered in the eCRF under scales and scores.

IQ-CODE

The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE; short version)

This assessment is directed at the patient's carer, family member or friend and is designed for them to complete. Generally, this test is completed without interference by a doctor or nurse, but it can be talked through with them if they need clarification.

Please give the questionnaire to patient's carer, family member or friend and ask them to follow the instructions for completing it.

How to calculate the final score of the test:

Scoring the IQ code

1 = Much improved

2 = A bit improved

3 = Not much change

4 = A bit worse

5 = Much worse

The electronic CRF will calculate the scores. To manually score the test, add up the result of each question (ie if 'Much improved' the result is 1 for that question), then divide this number by the total number of questions.

Record the final score of the test in the box below and also add this score to the patient's cognitive assessment record form.

$$\frac{\text{Sum of the results of all of the questions}}{\text{The total number of questions}} = \frac{\quad}{16} = \boxed{\quad}$$

Patient ID 01030 | Date entered study 06/03/2012 | Site 01 University College

[Return to patient](#)

Scales and scores

Cognition: IQ-CODE

1. IQ-CODE completed?

Yes

No

2. If not completed, please give the reason

3. IQ-CODE score

Number to 2 decimal places

4. Date completed

dd/mm/yyyy

Figure 27: IQ code form

MOCA (MONTREAL COGNITIVE ASSESSMENT): ADMINISTRATION AND SCORING INSTRUCTIONS

The Montreal Cognitive Assessment (MoCA) was designed as a rapid screening instrument for mild cognitive dysfunction. It assesses different cognitive domains: attention and concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, and orientation. Time to administer the MoCA is approximately 10 minutes. The total possible score is 30 points; a score of 26 or above is considered normal.

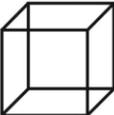
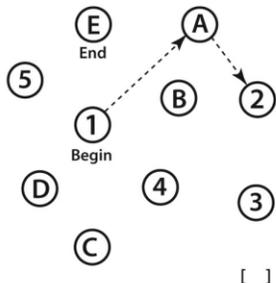
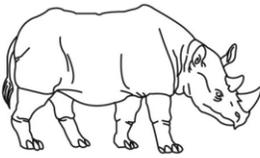
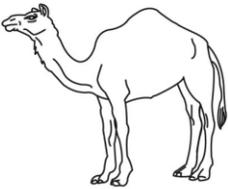
MONTREAL COGNITIVE ASSESSMENT (MOCA) Version 7.1 Original Version		NAME :	Date of birth :	POINTS																		
		Education :	DATE :																			
		Sex :																				
VISUOSPATIAL / EXECUTIVE		<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>Copy cube</p> </div> <div style="text-align: center;"> <p>Draw CLOCK (Ten past eleven) (3 points)</p> </div> </div>		___/5																		
		<input type="checkbox"/> Contour <input type="checkbox"/> Numbers <input type="checkbox"/> Hands																				
NAMING		<div style="display: flex; justify-content: space-around; align-items: center;">    </div>		___/3																		
MEMORY		Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td></td> <td>FACE</td> <td>VELVET</td> <td>CHURCH</td> <td>DAISY</td> <td>RED</td> </tr> <tr> <td>1st trial</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2nd trial</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		FACE	VELVET	CHURCH	DAISY	RED	1st trial						2nd trial						No points
	FACE	VELVET	CHURCH	DAISY	RED																	
1st trial																						
2nd trial																						
ATTENTION		Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [] 2 1 8 5 4 Subject has to repeat them in the backward order [] 7 4 2	___/2																			
LANGUAGE		Repeat : I only know that John is the one to help today. [] The cat always hid under the couch when dogs were in the room. []	___/2																			
ABSTRACTION		Similarity between e.g. banana - orange = fruit [] train - bicycle [] watch - ruler	___/2																			
DELAYED RECALL		<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tr> <td>Has to recall words WITH NO CUE</td> <td>FACE</td> <td>VELVET</td> <td>CHURCH</td> <td>DAISY</td> <td>RED</td> <td rowspan="2">Points for UNCUEDE recall only</td> </tr> <tr> <td></td> <td>[]</td> <td>[]</td> <td>[]</td> <td>[]</td> <td>[]</td> </tr> </table>	Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUEDE recall only		[]	[]	[]	[]	[]	___/5						
Has to recall words WITH NO CUE	FACE	VELVET	CHURCH	DAISY	RED	Points for UNCUEDE recall only																
	[]	[]	[]	[]	[]																	
Optional		Category cue Multiple choice cue																				
ORIENTATION		<input type="checkbox"/> Date <input type="checkbox"/> Month <input type="checkbox"/> Year <input type="checkbox"/> Day <input type="checkbox"/> Place <input type="checkbox"/> City	___/6																			
© Z.Nasreddine MD www.mocatest.org Normal ≥ 26 / 30		TOTAL ___/30 Add 1 point if ≤ 12 yr edu																				

Figure 28: MoCA

1. Alternating Trail Making

Administration

The examiner instructs the subject: "Please draw a line, going from a number to a letter in ascending order. Begin here [point to (1)] and draw a line from 1 then to A then to 2 and so on. End here [point to (E)]."

Scoring

Allocate one point if the subject successfully draws the following pattern:

1 -A- 2- B- 3- C- 4- D- 5- E, without drawing any lines that cross. Any error that is not immediately self-corrected earns a score of 0.

2. Visuoconstructional Skills (Cube)

Administration: The examiner gives the following instructions, pointing to the cube: "*Copy this drawing as accurately as you can, in the space below*".

Scoring: One point is allocated for a correctly executed drawing.

- Drawing must be three-dimensional
- All lines are drawn
- No line is added
- Lines are relatively parallel and their length is similar (rectangular prisms are accepted)

A point is not assigned if any of the above-criteria are not met.

3. Visuoconstructional Skills (Clock)

Administration: Indicate the right third of the space and give the following instructions: "*Draw a clock. Put in all the numbers and set the time to 10 past 11*".

Scoring: One point is allocated for each of the following three criteria:

- Contour (1 pt.): the clock face must be a circle with only minor distortion acceptable (e.g., slight imperfection on closing the circle);
- Numbers (1 pt.): all clock numbers must be present with no additional numbers; numbers must be in the correct order and placed in the approximate quadrants on the clock face; Roman numerals are acceptable; numbers can be placed outside the circle contour;
- Hands (1 pt.): there must be two hands jointly indicating the correct time; the hour hand must be clearly shorter than the minute hand; hands must be centred within the clock face with their junction close to the clock centre.

A point is not assigned for a given element if any of the above-criteria are not met.

4. Naming

Administration: Beginning on the left, point to each figure and say: *“Tell me the name of this animal”*.

Scoring: One point each is given for the following responses: (1) lion (2) rhinoceros or rhino (3) camel or dromedary.

5. Memory

Administration: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions: *“This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn’t matter in what order you say them”*.

Mark a check in the allocated space for each word the subject produces on this first trial. When the subject indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: *“I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time.”* Put a check in the allocated space for each word the subject recalls after the second trial.

At the end of the second trial, inform the subject that (s)he will be asked to recall these words again by saying, *“I will ask you to recall those words again at the end of the test.”*

Scoring: No points are given for Trials One and Two.

6. Attention

Forward Digit Span

Administration: Give the following instruction: “*I am going to say some numbers and when I am through, repeat them to me exactly as I said them*”. Read the five number sequence at a rate of one digit per second.

Backward Digit Span

Administration: Give the following instruction: “*Now I am going to say some more numbers, but when I am through you must repeat them to me in the backwards order.*” Read the three number sequence at a rate of one digit per second.

Scoring: Allocate one point for each sequence correctly repeated, (N.B.: the correct response for the backwards trial is 2-4-7).

Vigilance

Administration: The examiner reads the list of letters at a rate of one per second, after giving the following instruction: “I am going to read a sequence of letters. Every time I say the letter A, tap your hand once. If I say a different letter, do not tap your hand”.

Scoring: Give one point if there is zero to one errors (an error is a tap on a wrong letter or a failure to tap on letter A).

Serial 7s

Administration: The examiner gives the following instruction: “Now, I will ask you to count by subtracting seven from 100, and then, keep subtracting seven from your answer until I tell you to stop.” Give this instruction twice if necessary.

Scoring: This item is scored out of 3 points. Give no (0) points for no correct subtractions, 1 point for one correction subtraction, 2 points for two-to-three correct subtractions, and 3 points if the participant successfully makes four or five correct subtractions. Count each correct subtraction of 7 beginning at 100. Each subtraction is evaluated independently; that is, if the participant responds with an incorrect number but continues to correctly subtract 7 from it, give a point for each correct subtraction. For example, a participant may respond “92 – 85 –

78 – 71 – 64” where the “92” is incorrect, but all subsequent numbers are subtracted correctly. This is one error and the item would be given a score of 3.

7. Sentence repetition

Administration: The examiner gives the following instructions: “I am going to read you a sentence. Repeat it after me, exactly as I say it [pause]: I only know that John is the one to help today.” Following the response, say: “Now I am going to read you another sentence. Repeat it after me, exactly as I say it [pause]: The cat always hid under the couch when dogs were in the room.”

Scoring: Allocate 1 point for each sentence correctly repeated. Repetition must be exact. Be alert for errors that are omissions (e.g., omitting "only", "always") and substitutions/additions (e.g., "John is the one who helped today;" substituting "hides" for "hid", altering plurals, etc.).

8. Verbal fluency

Administration: The examiner gives the following instruction: “Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you to stop after one minute. Are you ready? [Pause] Now, tell me as many words as you can think of that begin with the letter F. [time for 60 sec]. Stop.”

Scoring: Allocate one point if the subject generates 11 words or more in 60 sec. Record the subject’s response in the bottom or side margins.

9. Abstraction

Administration: The examiner asks the subject to explain what each pair of words has in common, starting with the example: “Tell me how an orange and a banana are alike”. If the subject answers in a concrete manner, then say only one additional time: “Tell me another way in which those items are alike”. If the subject does not give the appropriate response (*fruit*), say, “Yes, and they are also both fruit.” Do not give any additional instructions or clarification. After the practice trial, say: “Now, tell me how a train and a bicycle are alike”. Following the response, administer the second trial, saying: “Now tell me how a ruler and a watch are alike”.

Do not give any additional instructions or prompts.

Scoring: Only the last two item pairs are scored. Give 1 point to each item pair correctly answered. The following responses are acceptable:

Train-bicycle = means of transportation, means of travelling, you take trips in both;

Ruler-watch = measuring instruments, used to measure.

The following responses are not acceptable:

Train-bicycle = they have wheels

Rulerwatch = they have numbers

10. Delayed recall

Administration: The examiner gives the following instruction: *“I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember.”* Make a check mark (✓) for each of the words correctly recalled spontaneously without any cues, in the allocated space.

Scoring: Allocate 1 point for each word recalled freely without any cues.

Optional:

Following the delayed free recall trial, prompt the subject with the semantic category cue provided below for any word not recalled. Make a check mark (✓) in the allocated space if the subject remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner. If the subject does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, *“Which of the following words do you think it was, NOSE, FACE, or HAND?”*

Use the following category and/or multiple-choice cues for each word, when appropriate:

FACE: category cue: part of the body multiple choice: nose, face, hand

VELVET: category cue: type of fabric multiple choice: denim, cotton, velvet

CHURCH: category cue: type of building multiple choice: church, school, hospital

DAISY: category cue: type of flower multiple choice: rose, daisy, tulip

RED: category cue: a colour multiple choice: red, blue, green

Scoring: No points are allocated for words recalled with a cue. A cue is used for clinical information purposes only and can give the test interpreter additional information about the type of memory disorder. For memory deficits due to retrieval failures, performance can be improved with a cue. For memory deficits due to encoding failures, performance does not improve with a cue.

II. Orientation

Administration: The examiner gives the following instructions: "Tell me the date today". If the subject does not give a complete answer, then prompt accordingly by saying: "Tell me the [year, month, exact date, and day of the week]." Then say: "Now, tell me the name of this place, and which city it is in."

Scoring: Give one point for each item correctly answered. The subject must tell the exact date and the exact place (name of hospital, clinic or office). No points are allocated if subject makes an error of one day for the day and date.

TOTAL SCORE

Sum all sub-scores listed on the right-hand side. Add one point for an individual who has 12 years or fewer of formal education, for a possible maximum of 30 points.

Cognition: MOCA

5. MOCA completed?

Yes

No

6. If not completed, please give the reason

7. MOCA total score

Number (up to 2 digits)

8. MOCA subscales - visuospatial/executive

Number (up to 1 digit)

9. MOCA subscales - naming

Number (up to 1 digit)

10. MOCA subscales - attention

Number (up to 1 digit)

11. MOCA subscales - orientation

Number (up to 1 digit)

12. MOCA subscales - language

Number (up to 1 digit)

13. MOCA subscales - abstraction

Number (up to 1 digit)

14. MOCA subscales - delayed recall

Number (up to 1 digit)

Figure 29: Screen to enter MoCA scores

QUALITY OF LIFE: EQ-5D-5L

EQ-5D is a standardized instrument for use as a measure of health outcome. It is designed for self-completion by respondents. You must provide the paper copy for the patient to complete.

The EQ-5D self-report questionnaire (EQ-5D) essentially consists of two pages comprising the EQ-5D descriptive system (see below) and the EQ visual analogue scale (VAS).

Under each heading, please **tick the ONE box** that **best describes your health TODAY**

MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed

I am moderately anxious or depressed

I am severely anxious or depressed

I am extremely anxious or depressed

COGNITION

I am able to remember most things, think clearly, and solve day-to-day problems

I am able to remember most things, but have a little difficulty when trying to think and solve day-to-day problems

I am somewhat forgetful, but able to think clearly and solve day-to-day problems

I am somewhat forgetful, and have a little difficulty when trying to think or solve day-to-day problems

I am very forgetful, and have great difficulty when trying to think or solve day-to-day problems

I am unable to remember anything at all, and unable to think/solve day-to-day problems

To score the descriptive system, a sequential scoring system should be used. For example, if the patient has ticked the responses like this:

MOBILITY

I have no problems in walking about

I have slight problems in walking about

I have moderate problems in walking about

I have severe problems in walking about

I am unable to walk about

SELF-CARE

I have no problems washing or dressing myself

I have slight problems washing or dressing myself

I have moderate problems washing or dressing myself

I have severe problems washing or dressing myself

I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities

I have slight problems doing my usual activities

I have moderate problems doing my usual activities

I have severe problems doing my usual activities

I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

COGNITION

- I am able to remember most things, think clearly, and solve day-to-day problems
- I am able to remember most things, but have a little difficulty when trying to think and solve day-to-day problems
- I am somewhat forgetful, but able to think clearly and solve day-to-day problems
- I am somewhat forgetful, and have a little difficulty when trying to think or solve day-to-day problems
- I am very forgetful, and have great difficulty when trying to think or solve day-to-day problems
- I am unable to remember anything at all, and unable to think/solve day-to-day problems

The score would be 123451. Please insert this score into the descriptive system box on the eCRF (see Figure 30).

The patient's 'X' on the 0-100 scale should be recorded under 'visual analogue scale' out of 100 on the eCRF (also see Figure 30).

Quality of life and disability scores

15. EQ-5D-5L (descriptive system) e.g. 123451

 Number (up to 6 digits)

16. Date EQ-5D-5L (descriptive system) completed

 dd/mm/yyyy

17. EQ-5D-5L (visual analogue scale)

 Number (up to 3 digits)

18. Date EQ-5D-5L (visual analogue scale) completed

 dd/mm/yyyy

Figure 30: EQ-5D-5L scores

MODIFIED RANKIN SCALE

Please provide an estimated score before the current event, and score on discharge from hospital or clinic. The score descriptions are listed over the page (Figure 32). Enter the scores for both on the eCRF, along with the date the Modified Rankin Scale was completed on discharge (see Figure 31).

19. Modified Rankin Scale (estimated score before the current TIA/stroke event) (help)

 Number (up to 1 digit)

20. Modified Rankin Scale (score on discharge from hospital or clinic) (help)

 Number (up to 1 digit)

21. Date Rankin completed on discharge

 dd/mm/yyyy

Figure 31: Modified Rankin Scores

Modified Rankin Scale	Date: __ / __ / __
-----------------------	--------------------

Total Score	Estimated score before the current event	
(0-6)	Score on discharge from hospital or clinic	

<p>Score Description</p> <p>0=No symptoms at all</p> <p>1= No significant disability despite symptoms; able to carry out all usual duties and activities</p> <p>2=Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance</p> <p>3=Moderate disability; requiring some help, but able to walk without assistance</p> <p>4=Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance</p> <p>5=Severe disability; bedridden, incontinent and requiring constant nursing care and attention</p> <p>6=Dead</p>

Figure 32: Modified Rankin Scale score descriptions

Management

Management

Management

1. Reversal of anticoagulation?

Yes
 No
 Unknown

2. If yes, was Fresh Frozen Plasma (FFP) used?
Yes ▾

3. If yes, was Octaplex used?
No ▾

4. If yes, was Fibrinogen used?
No ▾

5. Intravenous blood pressure treatment?

Yes
 No
 Unknown

6. If yes, was Labetalol used?
Choose... ▾

7. If yes, was Glyceryl trinitrate (GTN) used?
Choose... ▾

8. If yes, was Nitroprusside used?
Choose... ▾

9. If yes, was Calcium channel blocker used?
Choose... ▾

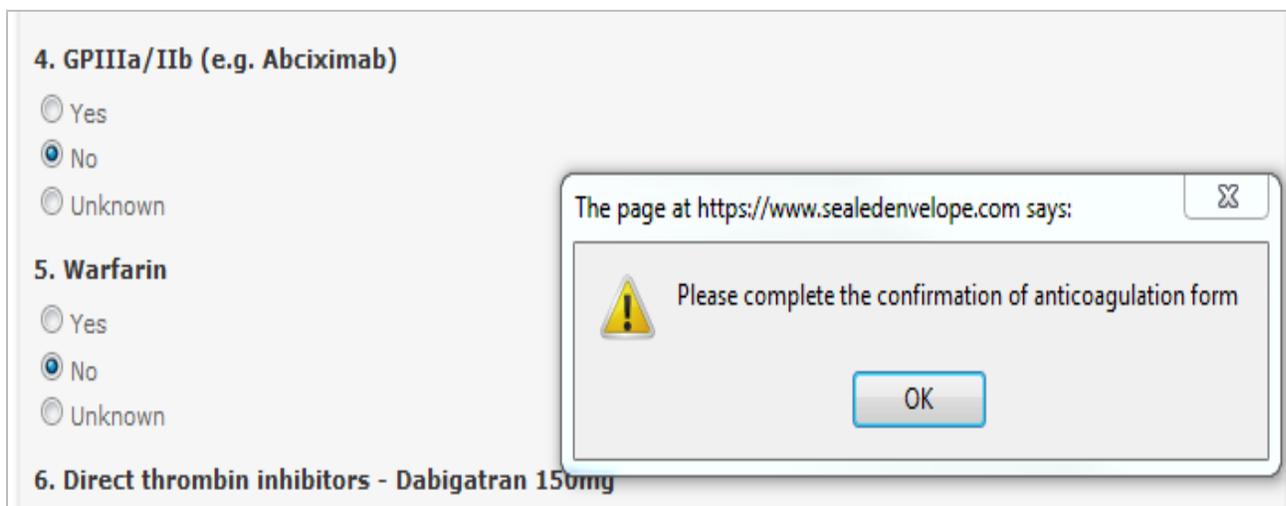
10. Calcium channel blocker used
Choose... ▾

Figure 33: Study II (ICH) Management form

DRUG MANAGEMENT

Complete the three drug management forms to provide accurate information on drugs on admission, drugs whilst in hospital, and drugs on discharge.

Study I (AF): It is important to note that if the patient does not start anticoagulants before discharge, a confirmation of anticoagulation form must be completed. A message will appear to inform you this form **MUST** be completed (see Figure 34).



The image shows a screenshot of a web form with three sections: 4. GPIIIa/IIb (e.g. Abciximab), 5. Warfarin, and 6. Direct thrombin inhibitors - Dabigatran 150mg. Each section has radio buttons for Yes, No, and Unknown. The 'No' option is selected in all three sections. A warning message box is overlaid on the right side of the form, containing a yellow warning icon and the text: 'Please complete the confirmation of anticoagulation form'. The message box also includes an 'OK' button and a close button (X) in the top right corner. The title of the message box is 'The page at https://www.sealedenvelope.com says:'.

Figure 34: Warning message to complete the confirmation of anticoagulation form if the patient has not started anticoagulation prior to discharge

FOLLOW UP

Initial routine follow up will be carried out by the Co-ordinating Centre by postal questionnaire. When data is received back, from patients and GPs, the data will be entered into the electronic data system under the relevant patient.

These forms are also available for sites to view and enter the data should the Co-ordinating Centre not be able to obtain this data, for either GP or Patient.

Local teams are requested to complete the follow up data by telephone. To enter the data, click on the relevant follow up time point within the patient home screen. Click on 'visit record'. This will enable you to access the rest of the form.

6 month follow-up		
Visit record (6 months)	Add	View Edit
GP 6 month follow up questionnaire	Add	View Edit
Patient 6 month follow up questionnaire	Add	View Edit
12 month follow-up		
Visit record (12 months)	Add	View Edit
GP 12 month follow up questionnaire	Add	View Edit
Patient 12 month follow up questionnaire	Add	View Edit
24 month follow-up		
Visit record (24 months)	Add	View Edit
GP 24 month follow up questionnaire	Add	View Edit
Patient 24 month follow up questionnaire	Add	View Edit
Events		
Death notification	Add	View Edit
Bleeding event	Add	
Cardiac event	Add	
Stroke or TIA	Add	

Figure 35: Follow up time points for study I (AF)

6 month follow-up		
Visit record (6 months)	Add	View Edit
GP 6 month follow up questionnaire	Add	View Edit
Patient 6 month follow up questionnaire	Add	View Edit
Events		
Death notification	Add	View Edit
Bleeding event	Add	
Cardiac event	Add	
Stroke or TIA	Add	

Figure 36: Follow up forms and event forms in patient for study II (ICH)

Visit record

The visit record screen enables a date to be entered of the ‘visit’, in this case when the questionnaire was completed.

Important Note: Please enter ‘yes’ to ‘Did the patient attend this visit?’

Visit record (6 months)

Attendance

1. Did the patient attend this visit?

Yes
 No

2. If yes, date of attendance

28/03/2012 

dd/mm/yyyy

3. If no, give reason

Figure 37: Visit record form for follow up

Once the visit form is completed, you can enter the Patient or GP follow up questionnaire by clicking on 'add', and entering the relevant data.

Important Note: When entering the data, a positive event is notified, the form will raise a message box requesting you complete the relevant Event form for the patient (see Figure 38 and Figure 39).

Problems with bleeding

2. Please indicate whether the patient has experienced any problems with bleeding in the last 6 months

Yes
 No

3. Problems with bleeding
 Choose... ▾

Anticoagulants

4. Is the patient currently taking anticoagulants?

Yes
 No

5. If yes, confirm the name of the drug they are taking
 Choose... ▾

6. If other, please state name of drug

7. If no, was the anticoagulant drug stopped because of bleeding?
 Choose... ▾

8. Is the patient currently taking any of the following?
 Choose... ▾

9. If other, please state name

The page at <https://www.sealedenvelope.com> says:

 Important! Please complete a bleeding event form

Figure 38: GP follow up form requesting a Bleeding event form to be completed

Since visit to hospital/clinic for stroke/TIA

10. Told by a doctor or other healthcare professional that had a stroke?

Yes
 No

11. Told by a doctor or other healthcare professional that had a TIA, mini-stroke, or transient ischaemic attack?

Yes
 No

12. Told by a doctor or other healthcare professional that had a brain haemorrhage?

Yes
 No

13. Had a sudden painless weakness on one side of body?

Yes
 No

14. Had a sudden numbness or a dead feeling on one side of body?

Yes
 No

15. Had a sudden painless loss of vision in one eye or both eyes?

Yes
 No

The page at <https://www.sealedenvelope.com> says:

 Important! Please complete a stroke or TIA event form

Figure 39: Patient follow up form requesting a Stroke or TIA form is completed

POSITIVE EVENT FORMS

Outcomes for the study are death, recurrent stroke/TIA, bleeding events, and cardiac events. Therefore we have provided forms to collect data regarding any patient events that occur during follow up. This are explained in this section.

Bleeding events form

This form must be completed by a member of the local research team when a patient recruited to the CROMIS-2 study has experienced a suspected or confirmed bleeding event. If when entering the form, a further event is notified, such as death, an electronic message will pop up requesting a Death Notification form is also completed (see Figure 40 overleaf). This way all outcome events can be collected.

The image shows a screenshot of a web-based form titled "Bleeding event". The form is partially obscured by a warning message box. The form content includes:

- Definition of Severity and Site of Bleeding Event**
- 1. Did the patient have a fatal bleeding event?**
 - Yes
 - No
- 2. Did the patient have symptomatic bleeding in any of the following areas?**
 - Yes
 - No
- 3. Intracranial (anywhere inside the skull)**
 - Choose... ▾
- 4. Intraspinal**
 - Choose... ▾
- 5. Intraocular (in the eye)**
 - Choose... ▾
- 6. Retroperitoneal**
 - Choose... ▾
- 7. Intra-articular (in the joint)**
 - Choose... ▾
- 8. Pericardial (around the heart)**
 - Choose... ▾
- 9. Intramuscular with compartment syndrome**
 - Choose... ▾
- 10. Gastrointestinal tract (e.g. blood in stool, haematemesis, blood in vomit)**
 - Choose... ▾
- 11. Did the bleeding cause a fall in haemoglobin level of ≥ 2 g /dL?**
 - Yes
 - No
- 12. Did the bleeding lead to transfusion of two or more units of whole blood or red cells**
 - Yes
 - No

The warning message box is titled "The page at <https://www.sealedenvelope.com> says:" and contains a yellow warning triangle icon, the text "Please complete the death notification form", and an "OK" button.

Figure 40: Bleeding Event form with message requesting death notification to also be completed

Cardiac event form

This form must be completed when a patient recruited to the CROMIS-2 study has experienced a suspected or confirmed cardiac event

Cardiac event

Details of the cardiac event

1. Date of suspected cardiac event
28/03/2012
dd/mm/yyyy

2. Was the event fatal?
 Yes
 No

Myocardial Infarction Report

3. Detection of rise and/or fall of cardiac biomarkers (preferably cardiac troponin) with at least one value above the 99th percentile of the upper reference limit (URL)
 Yes
 No

4. Symptoms of ischaemia (e.g. chest pain)
Yes

5. ECG changes indicative of new ischaemia (new ST-T changes or new left bundle branch block [LBBB])
No

6. Development of pathological Q waves in the ECG
No

7. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
No

8. Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischaemia, and accompanied by presumably new ST elevation, or new LBBB, and/or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.
No

9. If the cardiac event was not a myocardial infarction, please provide details of what the event was

Figure 41: Cardiac Event form

Stroke or TIA

This form must be completed when a patient recruited to the CROMIS-2 study has experienced a suspected or confirmed stroke or TIA event (including any form of intracranial bleeding).

Stroke or TIA

Details of suspected stroke or TIA

1. Date of onset of suspected stroke or TIA
29/03/2012
dd/mm/yyyy

2. Duration of symptoms (hrs/ mins)
05:00
hh:mm

3. Was the stroke fatal?
 Yes
 No

4. Type of stroke
Ischaemic (includes haemorrhagic transformation of infarct) ▼

5. Ischaemic mechanism
Cardioembolic ▼

Figure 42: Stroke/TIA form

Death Notification Form

Please complete this form for all deaths of patients recruited to the CROMIS-2 study. When this form has been completed, return to the CROMIS-2 study office with all reports you have available to you (i.e death certificate/post mortem report). If, when completing the form, a positive event is notified, a pop up message will appear asking you to complete the relevant form in addition to the death notification form (see Figure 43).

Patient ID 01030 | Date entered study 06/03/2012 | Site 01 University College London (Site #1), United Kingdom

[Return to patient](#)

Death notification

Details of death

1. Date of death

dd/mm/yyyy

2. Cause of death

3. Ischaemic stroke
 Yes
 No

4. Intracranial haemorrhage
 Yes
 No

5. Myocardial infarction (MI)
 Yes
 No

6. Pulmonary embolus
 Yes
 No

7. Sudden death (presumed cardiovascular)
 Yes
 No

8. Other vascular death
 Yes
 No

9. Please provide details of 'other vascular death'

10. Other non-vascular death
 Yes
 No

11. Please provide details of 'other non-vascular death'

The page at <https://www.sealedenvelope.com> says:

 Please complete the positive events form

Figure 43: Death notification form with message requesting a positive event form is completed

WITHDRAWAL FORMS

Please complete this form in the following circumstances:

1. If the patient or consultee wishes to withdraw from the study
2. If the patient or consultee wish to stop patients's ongoing participation in the study after the study has completed
3. If the patient is withdrawn from the study for any other reason

Withdrawal

Details of withdrawal

1. Date of withdrawal from the study
29/03/2012 
dd/mm/yyyy

2. Why was the patient withdrawn?
 Patient wish
 Other

3. Please list any further information

4. Has the patient agreed that the data already collected can be used?
 Yes
 No

Figure 44: Withdrawal form

Points to remember when completing this form:

- A patient has the right to withdraw from the study at any time and for any reason, without prejudice to their medical care. They are not obliged to provide a reason for their change of mind.
- Please clarify with the patients whether, despite withdrawing consent, they would agree for data collection to continue and any outstanding data collected.

Ensure the fact the patient has withdrawn is recorded in the patient notes.