DOCUMAS Study Updates

User Guide for Principal Investigators & Study Data Contacts

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1. Introduction

DOCUMAS is a clinical studies database and document management suite. Together, these components hold information about the status of each study through its lifecycle: feasibility, NHS permission (R&D approval), recruitment, monitoring, and study closure. DOCUMAS contains details of all clinical research studies taking place within the Imperial Academic Health Science Centre.

As part of our obligations to the National Institute for Health Research (NIHR), we are required to report regularly on our performance for both initiation and delivery of clinical research. To do this we require regular study updates and information from PIs and their study teams. To improve efficiency and consistency in this process, and to ensure high quality data, these study updates will be provided directly into the DOCUMAS database by study teams. This document provides instructions on how to access the system, and how to view and edit your data.

2. User Accounts & Nominated Study Data Contacts

Access to DOCUMAS – and the ability to change or update study data – is restricted to Principal Investigators (PIs) and to their nominated Study Data Contacts (SDCs). PIs will automatically receive DOCUMAS access when their study is initially entered onto the system. This will be in the form of a new user e-mail, containing log-in information.

One or more SDCs may also be nominated for a particular study. To nominate a SDC, the local study PI must e-mail their request to admin.documas@imperial.ac.uk with the following minimum information, copying in the proposed SDC:

- Study Reference Number (as assigned by the Joint Research Compliance Office (JRCO))
- Name of proposed SDC
- Job title of proposed SDC
- Email address of proposed SDC

SDCs must be substantive employees of Imperial College London or Imperial College Healthcare NHS Trust. A new user e-mail will be sent to the nominated SDC within 2 working days of receipt.

3. Viewing & Editing Study Data

3.1. Accessing DOCUMAS

DOCUMAS is a web-based system and is accessed from the following URL: https://icl.documas.eu

The system uses SSL (Secure Sockets Layer) as the industry standard security / encryption technology, which ensures that all data passed between the web server and your browser remain private.

To access DOCUMAS, enter your username and password, and click the Login button (Figure 1).

(Your initial predetermined DOCUMAS password is valid until 11 October 2013, after which you will be prompted to change to your own password. If you log in after this date, you will simply be prompted to make the password change immediately.)
You will then be presented with an introductory screen (Figure 2) from which you can select three options; 1) view the studies assigned to you, 2) change your profile/password, or 3) log out.

You can change your password by clicking on your name in the top right-hand corner of this page (Figure 3).
3.2. Study Summary Screen & Search Function

After clicking on 'Studies' at the top of the screen you will see a list of assigned clinical research studies, for which you are either named as the PI or listed as a nominated SDC (see Figure 2a). Studies assigned to you are displayed in table format, together with key dates and other information.

Use the navigation buttons to move through the list of studies (if you have more than 10 studies assigned).

Figure 3. Changing your password in Your Profile.

Figure 2a. Study Summary Screen Showing List of Assigned Studies
Clicking on any of the studies in the table will display summary data for that project in the right hand panel [see Figure 2b]. These fields are non-editable – please e-mail admin.documas@imperial.ac.uk if any of this information appears to be incorrect.

Quick Search button – click this button to search your own assigned studies using various criteria. Export to Spreadsheet – click this button to export your selected studies in .csv format

Click on any of the studies in the table and then click the "See full details" button at the top of the right-hand summary panel to view more study-specific information and to begin to enter data for this study. After clicking on the 'See full details' button, you will be presented with two tabs in which you can edit study information, labelled 'Key Study Dates & Status' and 'Recruitment Data' (Figure 3).

Figure 2b. Study Summary Screen Showing Additional Selected Study Details

Figure 3. First study data entry screen – “Key Study Dates & Status”. 
By default, you will be in the 'Key Study Dates & Status' screen (Figure 3).

3.3. “Key Study Dates & Status” Screen

Scrolling down slightly, you will an “Edit” button. Click on the “Edit” button at the bottom of the screen to begin to amend/edit/enter data in this screen. Four of the fields on the screen will now be editable (indicated by an ‘X’ underneath) – see Figure 4. The “Edit” button has become “Save”.

![Figure 4. Editing mode in “Key Study Dates & Status”.

You can click into each of the four key date fields to enter the necessary timeline information. You can either select the date from the calendar or type it in using your keyboard using the following format (dd-mm-yyyy).

NB The calendars show today’s date as a default. You can easily cycle to year and decade views by clicking the top of the calendar between the arrows.

The fields labelled “Target number of patients” and “Date agreed to recruit to target” are as agreed with the study sponsor and are shown for your information. They cannot be edited by you. If you feel these recruitment targets are incorrect, or require completion, please contact admin.documas@imperial.ac.uk

Select the current study status by clicking on the appropriate radio button.

Select a ‘BRC Study Type’ by clicking on the appropriate radio button.

Definitions for all fields are provided below. Hovering your mouse cursor over any of the fields on the screen will bring up some explanatory text.

Click the “Save” button to save your changes and either;

   Move to the “Recruitment Data” screen
   or
   Return to the study summary page using the “Back to all studies” button at the top of the page
3.4. “Recruitment Data” Screen

The Recruitment Data may cover several screens and you may need to scroll down to see the bottom of the page - see Figures 5a (top of the page) and 5b (bottom of the page).

Figure 5a. Top of the “Recruitment Data” screen.

Figure 5b. Bottom of the “Recruitment Data” screen.

Monthly recruitment data for your study can now be entered by calendar month. The range of months displayed should be appropriate for your study. If not, please email admin.documas@imperial.ac.uk to correct this.

Please enter a zero (0) in the appropriate month field if the study was open to recruitment but did not recruit any eligible patients.
A ‘recruit’ is defined as an individual who consented to join the study, and subsequently passed any screening or eligibility criteria.

Once you have finished entering recruitment data by month, click the “Save” button at the bottom of the screen.

The field entitled “Total Recruited to Date” at the top of the screen will be re-calculated to reflect the newly entered data once you have saved your entry.

Return to the study summary page using the “Back to all studies” button.

3.5. Logging Out

At the end of your session click ‘Logout’ at the top of the screen.

4. Study Updating Frequency

Study information can only be updated for studies which have received R&D Approval.

The Date of First Patient Consent field must be updated as soon as it is known.

The following fields must be updated every quarter of the financial year:

- Current Study Status
- Monthly Recruitment Figures

The following fields must be updated quarterly only if they have occurred in the previous quarter:

- Date of Site Initiation Visit
- Date of Final Patient Consent
- Date of Last Patient Last Visit

The quarterly reporting periods are defined by the NHS Financial Year as follows:

- Quarter 1: 1\textsuperscript{st} April – 30\textsuperscript{th} June
- Quarter 2: 1\textsuperscript{st} July – 30\textsuperscript{th} September
- Quarter 3: 1\textsuperscript{st} October – 31\textsuperscript{st} December
- Quarter 4: 1\textsuperscript{st} January – 31\textsuperscript{st} March

5. Automated Email Reminders

Date of First Patient Consent: An email will automatically be sent on the 5\textsuperscript{th} & 31\textsuperscript{st} calendar day following R&D Approval as a reminder to update this field as soon as it is known.

Quarterly Updates: An email will automatically be sent on the 1\textsuperscript{st} and 10\textsuperscript{th} working day following the end of each quarter as a reminder to update key study dates, study status, and monthly recruitment figures.

These ‘alert’ emails will be sent to the PI & Study Data Contact(s) for each study which has received R&D Approval and has not been confirmed as having status Closed, Abandoned or Withdrawn.
6. Field Definitions

6.1. Key Dates

The following definitions are used for the various fields in the “Key Study Dates & Status” Screen:

- **Site Initiation Date** – Date external sponsor carried out Site Initiation Visit which enabled study to begin recruiting at ICHT (if applicable – may be left blank if not applicable)

- **Date First Patient Consented** – Date that the first patient / volunteer consented to the study at ICHT (whether or not they subsequently undertook any study visits / procedures)

- **Date Final Patient Consented** – Date the last eligible patient / volunteer consented to the study at ICHT (i.e. final intended patient, not the most recent)

- **Date of Last Patient Last Visit** – Date of last visit of final patient to be recruited at ICHT; this should not be a forecast date but an actual date – leave blank if last patient has not yet had their last visit

- **Target number of patients** – Target number of patients to be recruited for this study at ICHT (as per contract / protocol / sponsor agreement)

- **Date agreed to recruit to target** – Agreed date by which target number of patients will be recruited (as per contract / protocol / sponsor agreement)

6.2. Study Status

The various options listed under ‘Study Status’ are defined as follows:

<table>
<thead>
<tr>
<th>Status</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viability Review Pending</td>
<td>Viability review is on-going within the Division. This occurs pre-award.</td>
</tr>
<tr>
<td>Funding Pending</td>
<td>Funding</td>
</tr>
<tr>
<td>Feasibility Review Pending</td>
<td>Feasibility review is on-going within the Division. This occurs post-award.</td>
</tr>
<tr>
<td>Pending R&amp;D Approval</td>
<td>Division Feasibility process complete. Pending R&amp;D Approval.</td>
</tr>
<tr>
<td>Site Initiation Pending</td>
<td>The project has R&amp;D approval but the Sponsor has not authorised recruitment to start</td>
</tr>
<tr>
<td>In Recruitment</td>
<td>The project has R&amp;D approval and the Sponsor has authorised recruitment to start</td>
</tr>
<tr>
<td>In Follow-Up</td>
<td>Recruitment to the study has ended but follow-up visits/data are still being conducted/collected</td>
</tr>
<tr>
<td>Close-Out</td>
<td>All patient visits have ended but work on the project continues (i.e. data queries, archiving preparation); the end of study notification has not yet been sent to the JRCO &amp; REC</td>
</tr>
<tr>
<td>Completed</td>
<td>The study was completed as planned and the end of study notification form has been submitted to the JRCO &amp; REC as applicable</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>The study was started but was not completed and has been withdrawn by the PI</td>
</tr>
</tbody>
</table>
| Abandoned | The project never started  
Or  
The funding application was not successful |
| Suspended | The project has been suspended by either the JRCO or the regulator |
| Inactive | The project is not currently active but is expected to restart |

1This status option will be updated by the Divisional Research Team or the Joint Research Compliance Office (JRCO).
6.3. Study Type

The various options in the drop-down box listed under 'BRC Study Type' are defined as follows (definitions are taken from the annual reporting requirements of the NIHR Imperial Biomedical Research Centre);

- **Clinical Trial (phase 0)** - human micro dosing studies involving a small number of subjects to gather preliminary data on a drug’s pharmacokinetics and pharmacodynamics

- **Clinical Trial (phase I)** - initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients

- **Clinical Trial (phase II)** - controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks

- **Clinical Trial (phase III)** - expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, to determine its safety, efficacy, and appropriate dosage

- **Clinical Trial (phase IV)** - post-marketing studies to delineate additional information including the drug’s risks, benefits, and optimal use

- **Device study**

- **Combined drug & device study**

- **Non-drug intervention (e.g. surgical)**

- **Biomarker study (observational)**

- **Diagnostic study (observational)**

- **Epidemiological study (observational)**

- **Screening study (observational)**

- **Other type of observational study**

6.4. Recruitment Data

Recruitment data field definitions are generally self-evident. Each month field should be completed with the number of eligible patients recruited that month (i.e. the number of patients that take part in the study and count towards the recruitment target). If no patients are recruited in a particular month then please enter 0 (zero) for that month – do not leave blank.

7. Help & Contact

If you require help using the system or you feel that information held on your study is incorrect please contact admin.documas@imperial.ac.uk.

Alternatively you can log a query using the contact form on http://www3.imperial.ac.uk/jointresearchoffice/healthcareresearchstudies/documas