

Clinical Data Systems Process

Background to the [OpenClinica](#) system - [Imperial Clinical Trials Unit \(ICTU\) – Clinical Data Systems](#)

PRE-AWARD

The costing process can be completed and turned around in a short timeframe from the time a request is received and reviewed by the Clinical Data Systems team (providing staff are not away on annual or sick leave, or away from the office in meetings)

Dept/Section Admin

All requests will need to be made within plenty of time before the funder's deadline, hence conforming to the college's [5-DAY RULE](#). If multiple requests are made on the final, or penultimate day, of the funder's deadline then your request for a costing is very unlikely to be turned around so quickly, if at all before the deadline.

**All requests should be sent to [Amanda Bravery](#) and [Lauren Noto](#).
Please copy in cds_services@imperial.ac.uk email address as this is monitored by several members of the team**

Once a costing has been generated and sent to JRO/Dept Admin from the **Clinical Data Systems** team, please ensure the costs are added to the InfoEd proposal correctly.

Clinical Trials using the OpenClinica system are a [CHARGE OUT FACILITY](#), please click on the link and scroll down to Directly Allocated Research Facilities for more information about what charge-out facilities are within college.

- The Clinical Data Systems costs should be added to the **MAIN PROPOSAL in the FIRST YEAR ONLY** (and not as a subproject for ICTU as the under-recovery should be borne by the department using Clinical Data Systems – *Only if SPH were using Clinical Data Systems would these costs fall under this department*).
THE EXCEPTION to this is for H2020 EU proposals – please see page 3 below
- The Clinical Data Systems costs should be added to the proposal as a Directly Allocated Cost with a clear description named “CLINICAL DATA SYSTEMS COSTS” and the category “Clinical Trials Clinical Data Systems” selected from the drop-down menu.
This will enable all Clinical Data Systems costs to be picked up on Oracle Discoverer reports and allow tracking of successful proposals which include Clinical Data Systems costs.
- Please also ensure the TRIAL NAME is included in the title of the proposal to allow for ease of tracking.
- **JRO/Dept, please ensure you let the CLINICAL DATA SYSTEMS team know the P-number afterwards for completeness.**

POST-AWARD

Once an offer/award is made to Imperial College and the JRO/Dept are informed of the successful application.

- The **JRO** will create a budgeting form and clearly show the **Clinical Data Systems** costs which have been awarded.

For FEC awards – Clinical Data Systems costs will be shown under the Directly Allocated heading with analysis code **182130**

For non-FEC awards – Clinical Data Systems costs will be shown under the Directly Incurred heading with analysis code **165134**

Amanda Bravery, Lauren Noto and Obi Umenyiora all need to be included in the “Award Set Up” email which goes to the PI and Dept

Once the award has been set up on the system the Clinical Data Systems costs must be incurred against the above headings.

JRO Team

For FEC awards, a recurring journal needs to be created pro-rata for the total facility budget for the **FIRST YEAR ONLY**. This will ensure ICTU recover their full costs for the usage of the Clinical Data Systems system throughout the lifecycle of the grant. **N.B. Check with Amanda Bravery if the recurring journal can be commenced immediately or if this should be delayed until further notice?**

Journal required:

Debit – (Award) Wxxx_Pxxxxx.**182130**
Credit – (ICTU) **WPCA.G24093.542130**

Clinical Data Systems team

For non-FEC awards, **NO** recurring journal is created; it will be the responsibility of the Clinical Data Systems team to create one-off journals for the **actual** costs incurred within the facility on an ad-hoc basis.

Journal required:

Debit – (Award) Wxxx_Pxxxxx.**165134**
Credit – (ICTU) **WPCA.G24093.165134**

In both instances above a robust auditable record must be kept within the Clinical Data Systems team to stand up to any potential audits by our funders. As the Clinical Data Systems costs for FEC awards are based on estimates, we can journal up to the full budget awarded, as some trials will cost more and some less but the full budget can be recovered.

Recovery of Costs

The under-recovery of the grant will be borne **by the department using** the facility, **not** the facility itself.

Exception – H2020 EU projects where a subproject is required

The difference with EU projects is that every cost incurred needs to have an auditable trail and back-up documentation to show how the costs were incurred and whether these are economical, reasonable, and eligible.

Pre-Award

Therefore, as there is no under-recovery on H2020 projects, when Clinical Data Systems is used on EU projects there should be a subproject set up on InfoEd against the main award, and therefore Clinical Data Systems will still recover ~100% of their costs, plus 25% overheads.

Post Award

The subproject will be set up under cost centre “WPCA”.

A clear breakdown of the budget must be shown on ICIS so the actual eligible costs can be incurred against each heading, as per the Clinical Data Systems Process. Each member of staff will need to be backed up by timesheets (Inc. ICT staff) and all other DI costs must have clear auditable trail of purchase.

Please note this principal would also be the same if other funders also wanted to see an auditable trial of costs incurred, so not just EU.

This works differently to the above procedure due to the audit requirement so even if Clinical Data Systems is being used within SPH, it still must have a separate subproject to distinguish between the costs under each cost centre.