National Cancer Control Programme

National Cancer Information System

NCIS GUIDE

For Recording Clinical Trial Participation in NCIS.Chart

1. Background

NCIS.Chart includes functionality for recording patient participation in a clinical trial as well as recommending them for a clinical trial in the Conference. This Guide explains how to utilise this functionality.

As further background the National Cancer Strategy 2017-2026 [1] includes a key performance indicator (KPI) to measure therapeutic clinical trial enrolment but does not provide an explicit definition of a Therapeutic Clinical Trial.

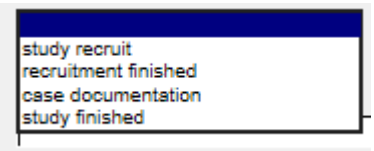
Following review of Irish and International clinical trial definitions as well as the definitions for clinical trials included in European Cancer Centre (ECC) accreditation models the NCCP Executive has agreed to align the definition of a Therapeutic Clinical Trial with the ECC definition. The following definition is agreed:

- All studies with ethical approval
- Studies can be non-interventional, interventional or diagnostic studies
- Biobank collections are excluded [2]

2. Setting up a clinical trial

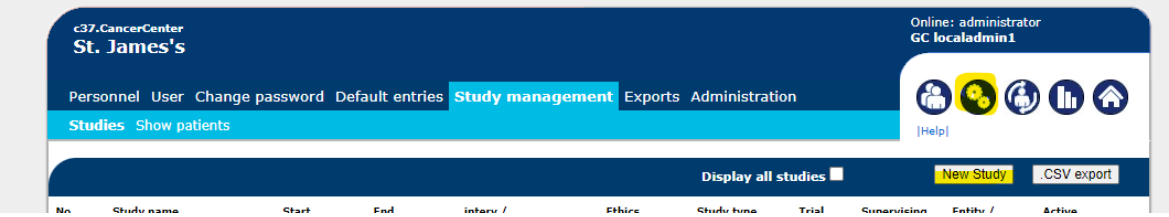
Trials can be entered in NCIS.Chart by case managers and administrators in the Study Management menu. Casemanagers and administrators can only set up a trial in the hospital(s) that they are assigned to. To edit a multi-site trial the user must have access to all the sites that the trial is assigned to.

There are many fields available when setting up a trial but only a small number are actually visible to normal users (in the conference form and tumour case), the visible fields are shown below.

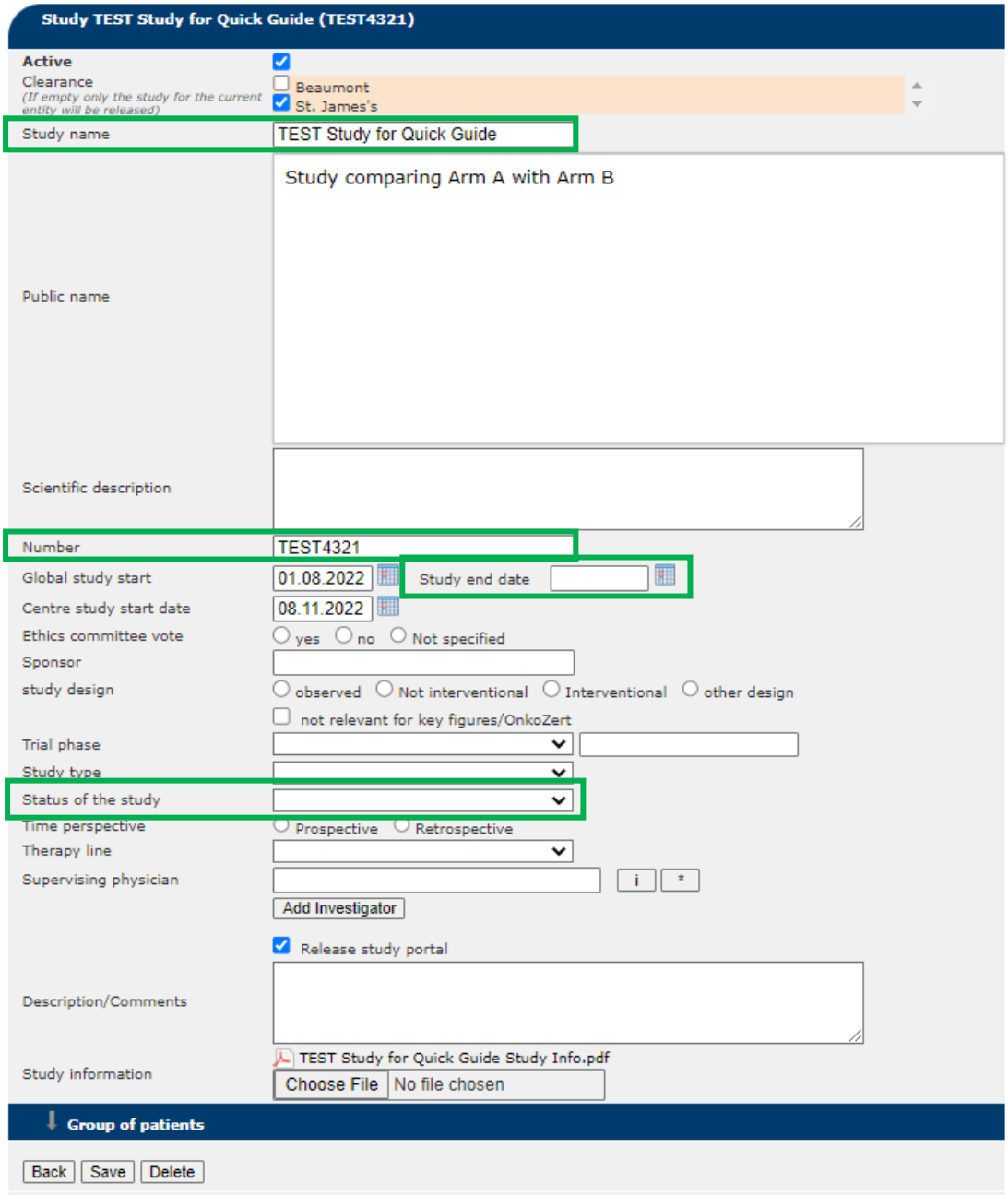
Field Name	Description	Appears	Definition
Study Name	The name of the study	Drop down list in Tumour Case and Conference Form	The name of the study
Number	The number of the study	Drop down list in Tumour Case and Conference Form	The number or code used by the sponsor to identify the trial
Status of the Study	This current status of the study, the options are: 	When "Study Finished" is selected the study will not appear in the drop down list in the Tumour Case or Conference Form	The current status of the study in the hospital
Study end date	The study end date	When entered "(completed)" will appear by the study name in the drop down list on the patient's tumour case and conference form	The study end date in the hospital

[1] Department of Health National Cancer Strategy 2017-2026 https://assets.gov.ie/9315/6f1592a09583421baa87de3a7e9cb619.pdf
[2] It is possible to add all trial types to NCIS and log participation, it will then be possible to exclude trial types from reports as appropriate e.g. reporting for the definition as agreed for National Cancer Strategy 2017-2026.

To enter a new trial in NCIS.Chart click on Settings, then the Study Management Tab, followed by New Study.



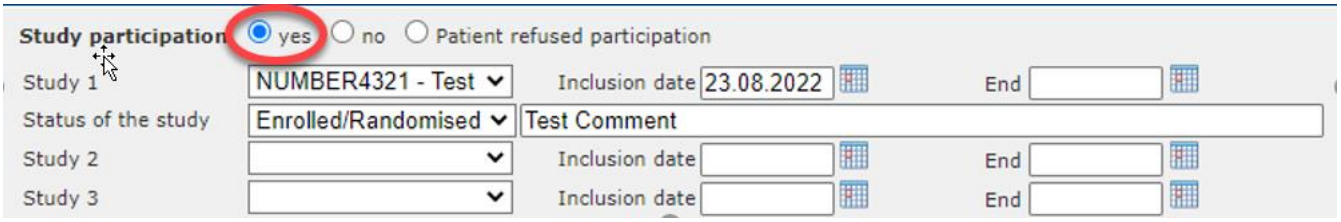
The following screen appears, it is advised to tick the hospital clearance button so that the trial appears correctly in your hospital only. Tick the active button also so the trial is visible. The recommended fields for completion are shown with green boxes. All other fields serve little purpose as they are only visible in this screen and not to standard user accounts.



3. Recording participation in a clinical trial

Clinical Trial participation can be recorded in the patient's tumour case. Scroll to the end of the tumour specific dataset and click on the "yes" radio button for study participation.

Further fields now appear that allow the Study to be chosen, the Study status of the patient, the date the patient was included in the study and the date the patient was off study. There is also a free text box for additional information if required. The patient can be added to up to three studies per tumour case.

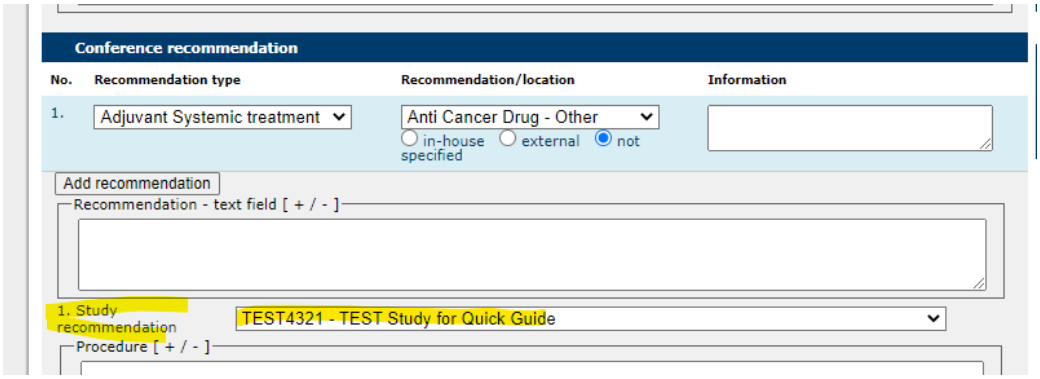


The following options are available from the "Status of the Study" drop down[3]. These options were agreed by the NCIS Implementation Group to align as closely as possible to participation reporting requirements at the time of writing.

Drop Down Option	Description
Did not consent	Eligible patients are referred and given information about the trial. The patient has the right to refuse consent and participation in the trial
Screen failed	If the patient does not meet the eligibility criteria, they are considered a screen failure. Often informed consent may be required for a screening phase of the trial as investigations may be required to confirm eligibility
Enrolled/Randomised	If eligibility is confirmed and the patient consents, they are enrolled or randomised on to the trial
Other	If none of the defined options are relevant

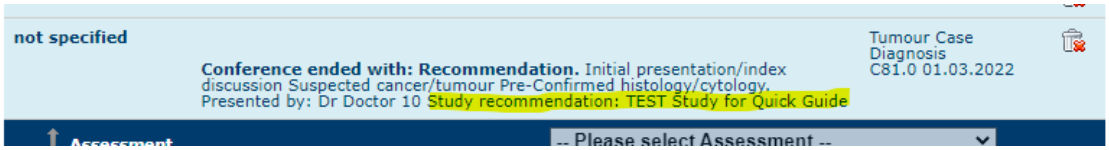
4. Recording a recommendation for a clinical trial in MDM (Conference)

In the conference form choose the desired clinical trial from the study recommendation drop down list.



The study recommendation now appears in the summary view in the tumour case.

[3] Note the "Status of the Study" in the tumour case refers to the patients study status while the "Status of the Study" in Study Management refers to the status of the study in the hospital. In a future version these fields will be labelled differently for improved distinction.


not specified
Conference ended with: Recommendation. Initial presentation/index discussion Suspected cancer/tumour Pre-Confirmed histology/cytology.
Presented by: Dr Doctor 10 Study recommendation: TEST Study for Quick Guide
Tumour Case Diagnosis
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-- Please select Assessment --