

# **FightMND's Grant Management System Manual: Submitting a Clinical Trial or Drug Development LOI and Grant**

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# Stage 1: Submitting a Letter of Intent (LOI)

## Step 1

Navigate to <https://fightmnd.fluxx.io/> in your browser



FightMND

Login Now:

Username

Password

[Reset or create password](#)

New to the Grants Portal?

Create Your Organizational Profile

In order to be considered for funding, the first step is for you to introduce yourself and tell us about your organization. Please click on the "Create an account Now" button below to start. You will not be able to edit your profile after submission, so please ensure you have entered accurate information (including email address) when completing the registration form.

## Step 2

If you have more than one user profile, select "Grantee" then continue to login. Otherwise, you will automatically be redirected to the Grantee portal.

Which Profile would you like to use?

Grantee

Reviewer

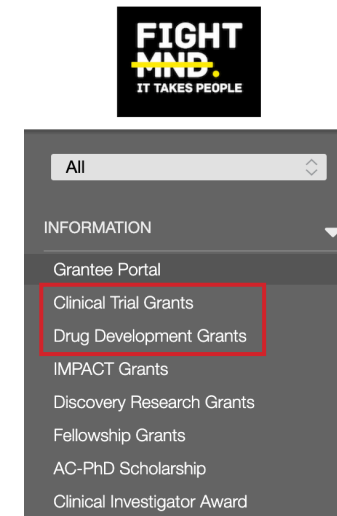
### Step 3

You will see the grantee portal welcome page.



### Step 4

Navigate to the left of the page and select the type of grant you wish to apply for. In this case, click on “Clinical Trial Grants” or “Drug Development Grants”



## Step 5

A page will appear detailing a summary of the type of grant being applied for. Click on the green “Apply for a grant” button if you wish to apply for this grant scheme

### Clinical Trial Grants – CTGs

Clinical Trials grants support phase II/III clinical trial of novel, high potential treatments in Motor Neurone Disease/Amyotrophic Lateral Sclerosis (MND/ALS) within the Australian Clinical Trials Consortium of hospitals.

The call for clinical study proposals is intended for academic-industry partnerships including but not limited to pharmaceutical, bio-therapeutic/biotechnology companies, academic institutions and universities, hospitals, and MND researchers throughout the world.

Up to AUD \$1,800,000 in support from FightMND is available per grant.

Potential Phase II/III clinical trials should include therapeutic interventions that have:

1. A pharmacodynamic marker that can measure whether the targeted pathway of interest has been affected;
2. A plan to collect samples for biomarker studies; and
3. Shown promising efficacy in at least two (2) MND disease models, one of which must be a representative model of human sporadic MND (if targeted to sporadic MND).

Industry partnership applications are strongly encouraged with shared funding proposals.

Note: It is NOT an Australian Regulatory requirement for drugs to have an IND submission prior to commencement of projects in Australia.

Since infrastructure support is provided by this grant, applicants should contact FightMND prior to their grant submission to collaborate on the budget portion.



## Step 6

A form will appear for you to complete your Letter of Intent. Please fill in all relevant information relating to Administering Organisation, Primary Investigator and Letter of Intent. Please note, fields in bold are compulsory fields and must be completed for the LOI to be submitted.

Information entered into the portal does not automatically save, so please periodically click “Save” to avoid losing your data.

The screenshot shows a dark blue header with the ID: CTG-202210-00503 and Program: CTG. Below the header is a 'Request Status' section with a progress bar showing 'Draft' as the current status. A red 'Please note' message states: 'The portal does not autosave; therefore, you must click the [Save] button to ensure your data will not be lost.' Below this is a 'Table of Contents' section with links for 'Primary Investigator Information', 'Administering Organisation', and 'Letter of Intent (LOI)'. The 'Primary Investigator Information' section contains four input fields: 'Prefix', 'First Name', 'Middle Name', and 'Last Name'. At the bottom right, there are three buttons: 'Save' (highlighted with a red arrow), 'Save and Close', and 'Cancel'.

## Step 7

Upload your Letter of Intent (LOI) and CV as PDF files (Maximum file size 5MB each) by clicking on the green + symbol to bring up an upload box.

**Upload the letter of intent for the specific research scheme (maximum 3 pages)**  
**Upload the CV of the Primary Investigator**

CV	+
Letter of Intent (LOI)	+

Letter Of Intent (LOI) Documents

Upload files  
Select or drag files then start upload

Filename	Size	Status
Drag files here.		

Add files Start upload

Click on “Add files” and locate the appropriate file in your computer. Once selected, click “Open”. The file will appear in the upload box. Click “start upload” to begin uploading this file into the system.

Once the file upload is complete, it will indicate 100% and the upload box will indicate “Upload complete!”. Close the upload box to return to the application.

Repeat this process for the LOI and CV separately. Once uploaded, they will appear in “Letter of Intent (LOI) Documents” below

## Step 8

When you have completed all fields, uploaded your proposal and timeline, and are ready to submit your application, click on “Save and Close”.

A summary of your application appears. Check all your information, and click edit in the top right corner to go back to your application if needed. If all information is correct and you are ready to submit, click on the “Submit” button on the bottom right corner.

ID: CTG-202210-00503  
Program: CTG

Amount Recommended:

Request Status

Draft With Applicant Review Active

**Bold indicates compulsory fields**

Status **Draft**

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[Primary Investigator Information](#)  
[Administering Organisation](#)  
[Letter of Intent \(LOI\)](#)

Primary Investigator Information

Prefix:

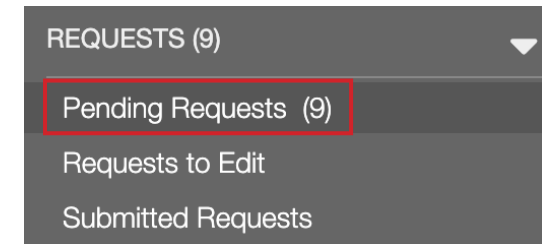
First Name:

Middle Name:

Last Name:

Withdraw Submit

Your LOI is now submitted to FightMND for consideration. It is stored in “Pending Requests” for your records.



# Stage 2: Submitting a full application

## Step 1

If your LOI has been invited for full application, you will receive an email from our research team (fightmnd@fluxx.io).

## Step 2

Log back in to the FightMND Fluxx Portal as described in Stage 1, step 1 and step 2

## Step 3

Your application will now be under “Requests to Edit”. Click on “Requests to Edit” then select the application you wish to proceed with. It will appear on the right of the screen to view. Click on “Edit” in the top right corner to return to the application.

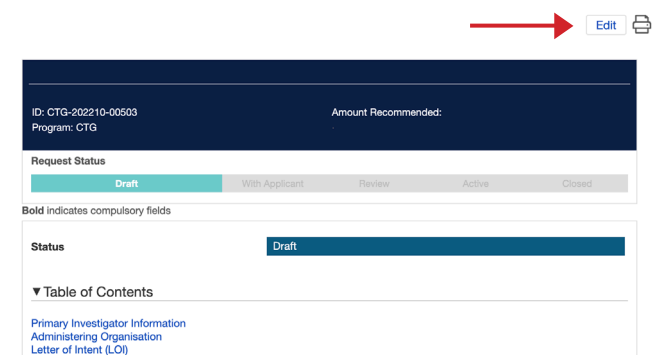
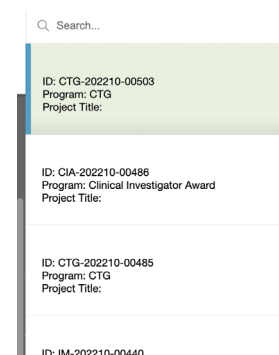
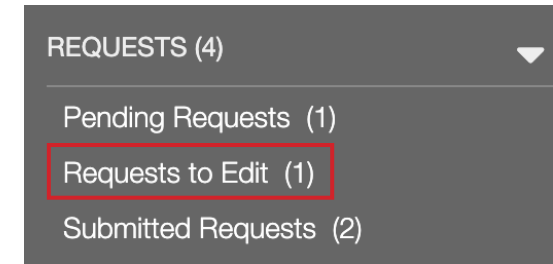
Letter of Intent: Successful - Invitation to submit full application

Dear :

Thank you for submitting your Letter of Intent for the 2022 FightMND CTG Grant round. This email is to inform you that following review, you are invited to submit a full application. Please log into the FightMND grants portal to submit your full application at <https://fightmnd.fluxx.io/>. Full applications are due by 6pm Australian Eastern Daylight Time (AEDT) on April 1, 2022.

Please confirm the receipt of this notification by contacting [researchgrants@fightmnd.org.au](mailto:researchgrants@fightmnd.org.au), and please don't hesitate to contact the FightMND team if you have any questions surrounding your submission

Kind regards,  
FightMND Research Team





#### Step 4

The full application form will now be available to complete. Please complete all sections of the full application (some fields will be pre-completed based on your LOI submission). Note that fields in bold are compulsory fields and must be completed to be able to submit your application.

The portal does not automatically save your information, so please periodically click “Save” at the bottom of the page to avoid losing your data.

#### Step 5

Please upload your project proposal and timeline as PDF files (maximum file size 5MB) in to the form. Click on the + symbol to bring up an upload box.

Click on “Add files” and locate the appropriate file in your computer. Once selected, click “Open”. The file will appear in the upload box. Click “start upload” to begin uploading this file in to the system.

Once the file upload is complete, it will indicate 100% and the upload box will indicate “Upload complete!”. Close the upload box to return to the application.

Repeat this process for the Proposal and Gantt Chart Timeline separately.

**Proposal** - Upload the proposal as a single PDF inline with grant criteria guidelines for the relevant schemes. Include all attachments and additional information (e.g. letters of support) as part of the proposal document (max 5MB)

**Timeline - Gantt Chart Format** - Upload a PDF of the project timeline in Gantt format, stating the timeline for delivery of key aims, experiments and milestones.



Proposal	+
Timeline	+

## Step 6

To enter your high-level budget, click on the green + symbol to open the high-level budget box

You will need to create a new entry for each year. Enter “Year 1” in to “Budget Year” and the approximate dates this year will cover.

Budget +

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No Budget have been added

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Add Budget ×

**Grant Summary Information**

Organization Name: FightMND  
Amount:  
Request ID: CTG-202210-00504  
Start Date:  
End Date:

**Budget Year**

**Start Date**

**End Date**

Then enter total budget amounts for the relevant categories provided. You only need to enter amounts for the budget categories you require, leave blank if you are not requesting funding for a particular category. If you require additional categories not covered, manually enter them in the form.

Add Budget ✕

Budget Details

Item	Budgeted
Salary Costs	<input style="width: 100%;" type="text"/>
CRO	<input style="width: 100%;" type="text"/>
Data Management	<input style="width: 100%;" type="text"/>
Ethics, Governance and Admin	<input style="width: 100%;" type="text"/>
Central Costs	<input style="width: 100%;" type="text"/>
PK/PD and Biomarker analysis	<input style="width: 100%;" type="text"/>

When complete, click “Save”. Your Year 1 budget has now been saved.

Click on the green + symbol and repeat this process for Year 2 and any subsequent grant years required. A summary of your year-by-year budget can be seen in the form.

#### Budget 🔍 +

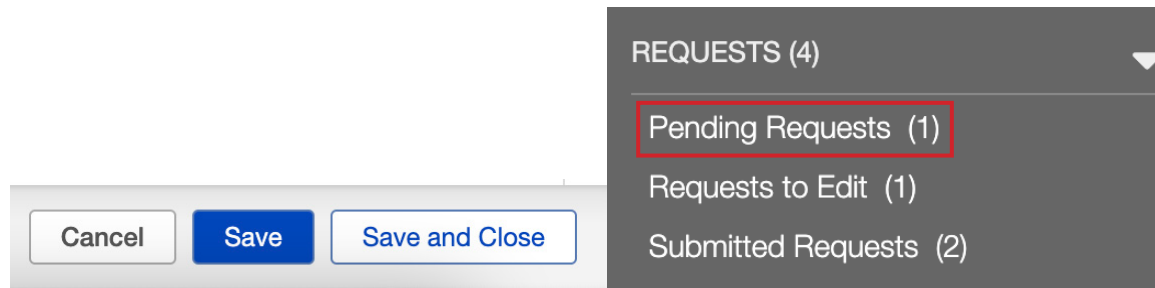
Budget Period	Budget	Actual	
1: 1/1/2023 to 31/12/2023	150,000	0	📄 ⊖
2: 1/1/2024 to 31/12/2023	150,000	0	📄 ⊖
<b>Total</b>	<b>300,000</b>	<b>0</b>	

#### Budget Snapshot

	1		2	
	1/1/2023 to 31/12/2023		1/1/2024 to 31/12/2023	
	Budget	Actual	Budget	Actual
Salary Costs	100,000		100,000	
CRO				
Data Management				
Ethics, Governance and Admin				

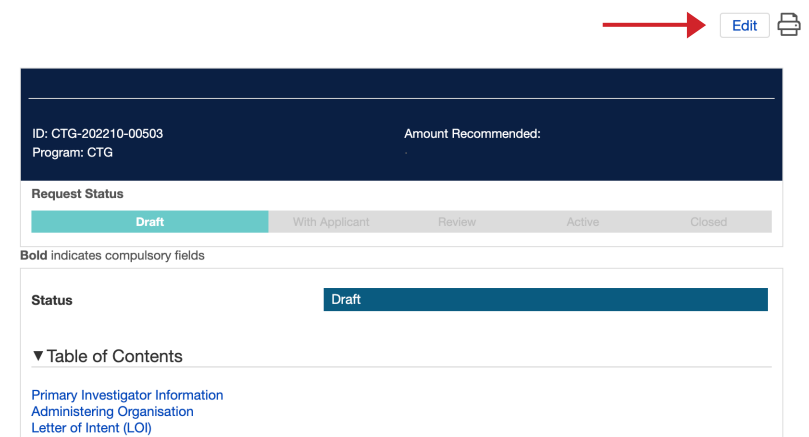
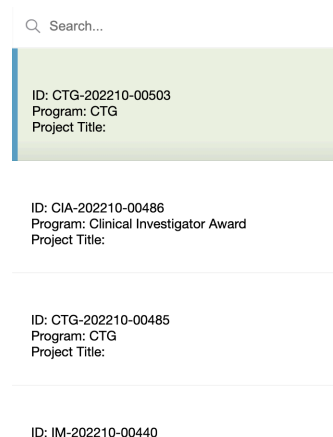
## Step 7

At any time, you can save your application and return to it later. Click on “Save and Close” at the bottom of the form. Your application will then appear in the “Pending Requests” on the left side of the portal (you may need to refresh the page to see it come up).



## Step 8

To continue a saved application, click on “Pending Requests”. A list of your saved applications will appear. Click on the one you wish to continue, it will be highlighted green in the list and will appear to the right, then click “Edit” in the top right corner to continue the application.



## Step 9

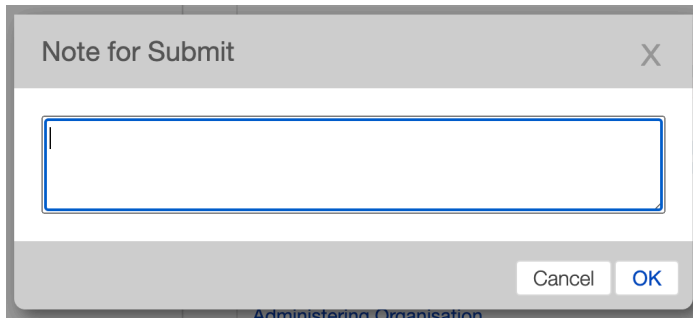
When you have completed all fields, uploaded your proposal and timeline, and are ready to submit your application, click on “Save and Close”.

A summary of your application appears. Check all your information again, and click edit in the top right corner to go back to your application if needed. If all information is correct and you are ready to submit, click on the “Submit” button on the bottom right corner.

The screenshot displays the FightMND application summary interface. On the left is a dark sidebar with the 'FIGHT MND. IT TAKES PEOPLE' logo at the top and a navigation menu with categories: FightMND, ORGANIZATIONS (1), PEOPLE (1), REQUESTS (4), GRANTS, and REPORTS. The 'REQUESTS (4)' section is expanded, showing 'Requests to Edit (1)' with a red notification icon. The main content area features a search bar, a notification for '1 Update Available', and a summary card for 'FightMND' with ID: CTG-202210-00504, Program: CTG, and Project Title: Test 1. Below this is a 'Request Status' progress bar with stages: Idea, New (active), Review, Active, and Closed. A red warning banner states 'No Budget Attached. Attach budget before submitting'. A 'Table of Contents' section lists links for Primary Investigator Information, Administering Organisation, Full Application, Documents, Budget, and Grant Terms Information. The 'Primary Investigator Information' section shows 'Prefix: Ms' and 'First Name: Sarah'. At the bottom right, a green 'Submit' button is highlighted with a red arrow. Another red arrow points to an 'Edit' button in the top right corner.

## Step 10

A pop-up may appear asking you to add notes to your submission. This is optional. If you have any additional notes you wish FightMND to see relating to this submission, add it here. Otherwise, leave the box blank and click OK.



The image shows a dialog box titled "Note for Submit" with a close button (X) in the top right corner. The main area of the dialog is a large, empty text input field with a blue border. At the bottom of the dialog, there are two buttons: "Cancel" and "OK". Below the dialog box, the text "Administering Organisation" is partially visible.

## Step 11

The proposal is now submitted to FightMND for peer review. You are able to view and print your submitted application (but not edit it) in the "Submitted requests" menu on the left side of the grantee profile.

An email will be sent to the Primary Investigator confirming submission of the grant application with an application ID. Please use this ID number in all correspondence with FightMND concerning your application.