Application Submission- User Manual - SMDI

IMPORTANT INSTRUCTIONS

1. All the mandatory fields marked with * have to be filled.
2. Do not use any special character while filing the form (i.e $,%,#, ^)
3. In case you have any queries or questions, please contact the PMA Team - LSSSDC:
    - Mrs. Madhu Rupa | Sr. Consultant | MADHU@LSSSDC.IN | + 91+91 9810186773
    - Mrs. Neha Sharma | Project Manager | NEHA.SHARMA@LSSSDC.IN | +91 8178357429
    - Ms. Chitra Kanwar| Project Coordinator | CHITRA.KANWAR@LSSSDC.IN | +91 9773982613
4. All the creatives and supporting documents should be uploaded in the correct format.
5. Ensure that all information is entered correctly. Once the form has been submitted, it cannot be changed.

Dear Applicant!

Thank you for your interest in the **Strengthening of the Medical Device Industry (SMDI) Scheme**! Please go through the following guide to register and fill in the forms of the 2 Sub - Schemes of the SMDI scheme:

1. Marginal Investment Scheme for Reducing Import Dependence
2. Medical Device Clinical Studies Support Scheme

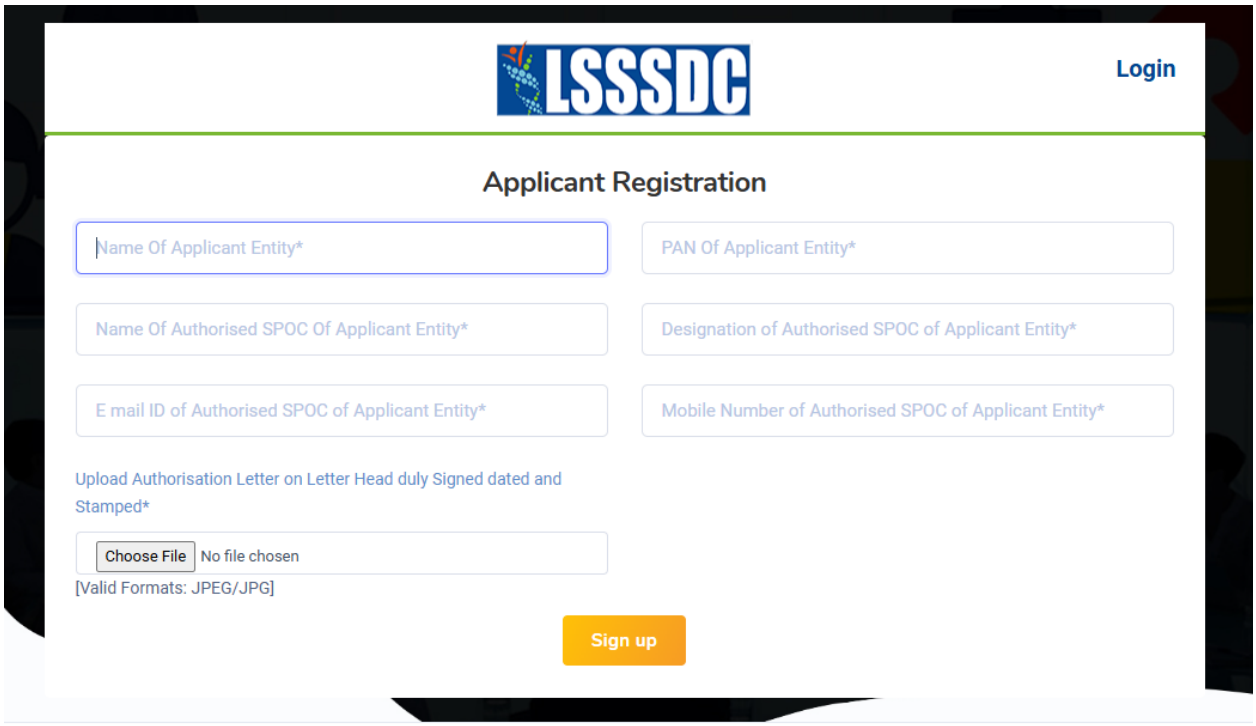
Medical Device Clinical Studies Support Scheme

Step 1: On the SMDI.LSSSDC.IN home page first click on the desired scheme: **Medical Device Clinical Studies Support Scheme:**

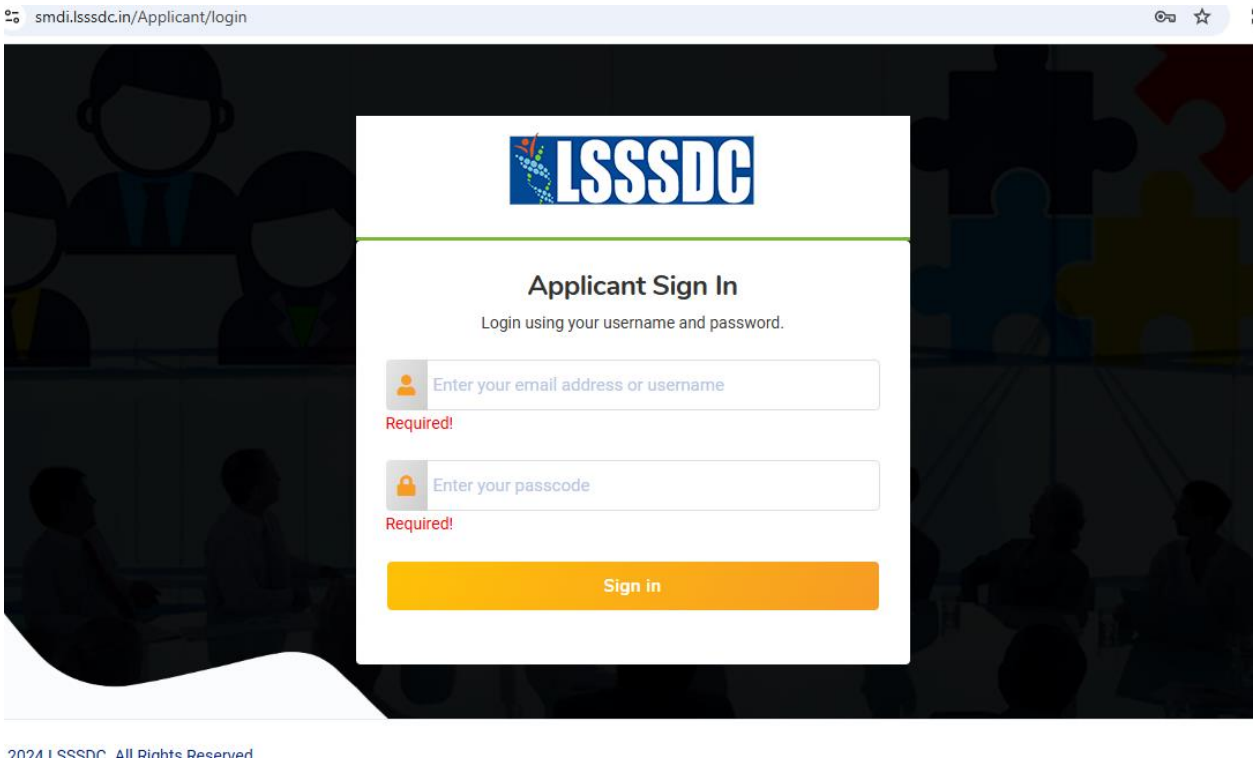
Step 2: The following page will appear, fill in the given details to register yourself. Kindly keep the following instructions in mind before filling these details:

1. The name of the Applicant Entity will be the name of the Organisation/Institution.

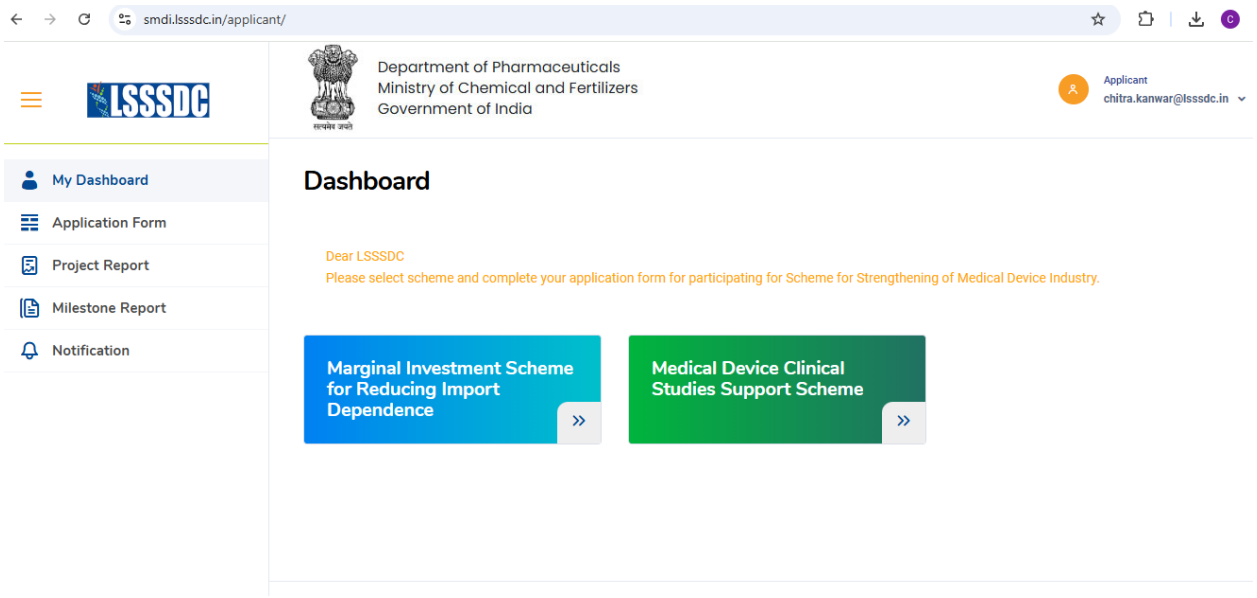
2. PAN will be of the Single point of Contact (SPOC).
3. The name of the authorised SPOC will be the same as the Authorization Letter.
4. Kindly make sure to upload the Authorisation Letter on Letter Head of your organisation/institution duly Signed, dated, and Stamped* which authorises you to apply on behalf of your organisation/institute.
5. After filling all the details click “Sign Up” and your login details will be sent to the SPOC Email ID.



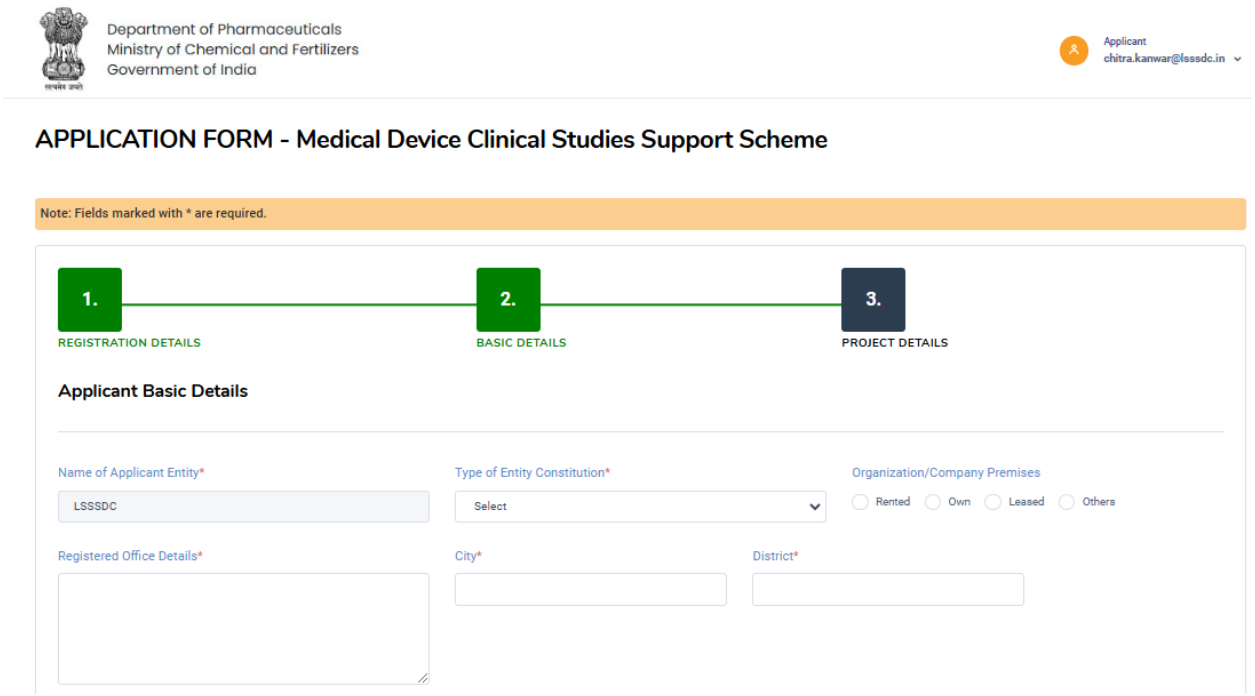
Step 3: After clicking on LOGIN, you will be taken to the following page where you will have to fill in the User ID and Login Password sent on your email:



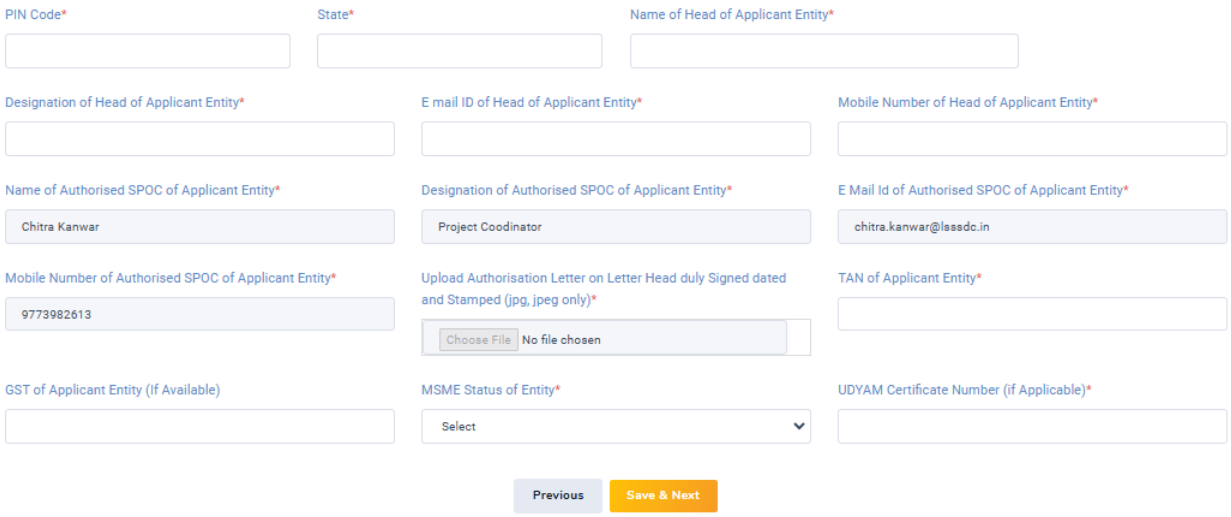
Step 4: On the Applicant Dashboard, first click on the desired scheme: **Medical Device Clinical Studies Support Scheme:**



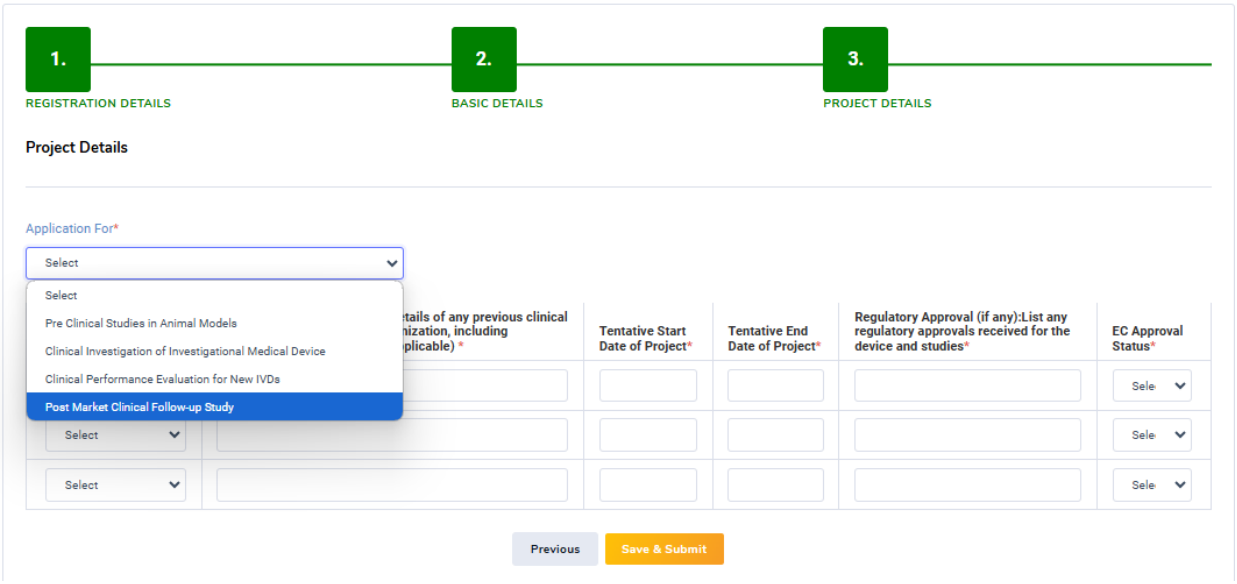
Step 2: You will then be directed to the application form for the Medical Device Clinical Studies Support Scheme, where you will have to fill the **"Basic Details"** Section.



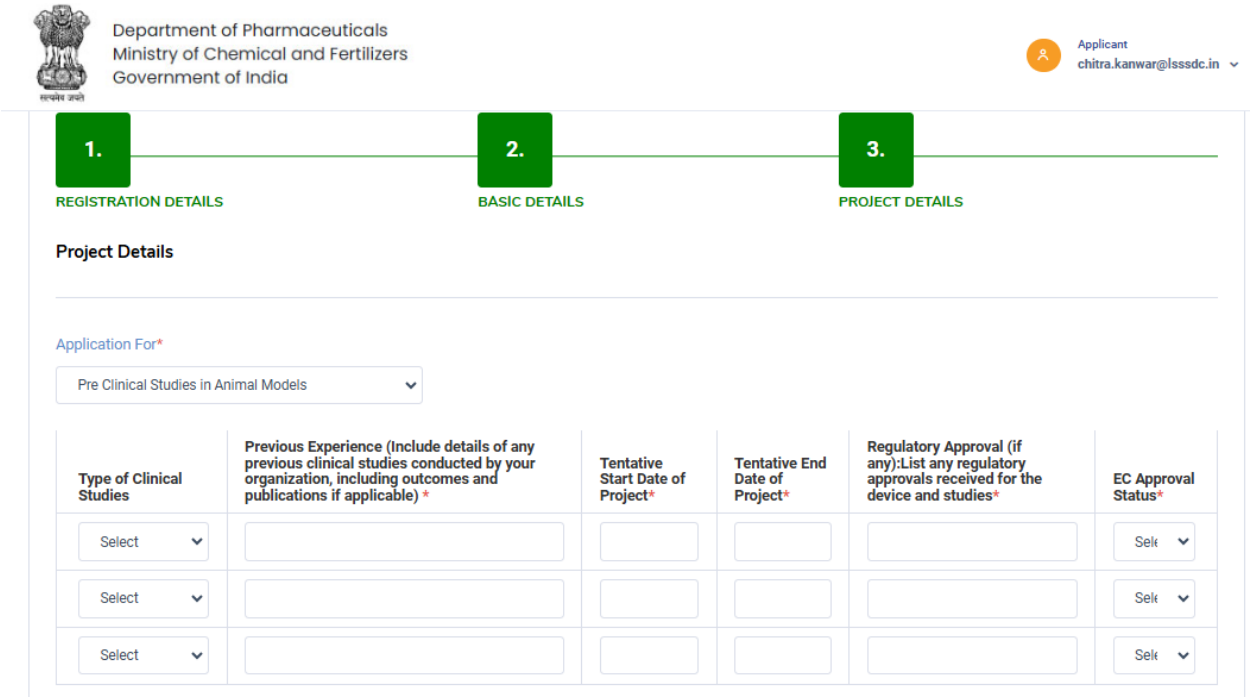
Step 3: The following details are to be filled in the **"Basic Details"** section, After click the **"Save & Next"** button:



Step 4: You will be directed to the "**Project Details"** section, in which you will have to select 1 of the 4 types of Clinical Studies:



Pre Clinical Studies in Animal Models



The **Project Details** for “Pre Clinical Studies in Animal Models” has the following sub-sections:

1. Device Information:

Project Details for Pre Clinical Studies in Animal Model

Device Information

Name of the Medical Device*

Device Risk Classification (IMDR 2017)*

Intended Use of the Product*

Device Description*

Technical Specifications*

2. Pre-clinical Study Details:

Pre-clinical Study Details

Select Study Design*
Select

Study Design (List of tests Perform) Upload Document (PDF)*
Choose File No file chosen

Expected date of Commissioning*

Animal Model Testing details*

Animal Model Testing details Upload Document (PDF)*
Choose File No file chosen

Proposed Study Timeline (activity-wise schedule)*

Proposed Study Timeline (activity-wise schedule) Upload Document (PDF)*
Choose File No file chosen

3. Study Site Details:

Study Site Details

Name of the Laboratory/Institute*

Address*

Process Detail of conducting pre-clinical study*

Process Detail of conducting pre-clinical study Upload Document (PDF)*
Choose File No file chosen

Expected Outcomes *
Select

Mode of Implementation*
Select

Applicant Role *
Select

Grant to be Claimed by*
Select

Test License Number (if Available)

4. Financial Details:

Financial Details

Estimated Total Cost of the Study (Amount in INR)*

Estimated Total Cost of the Study (Amount in INR) Upload Document (PDF)*
Choose File No file chosen

Requested Funding Support as a grant from the Government of India (on a reimbursement basis) (Amount in INR)*

Means of Finance (Other sources of funding) (Amount in INR)*

Previous Save & Submit

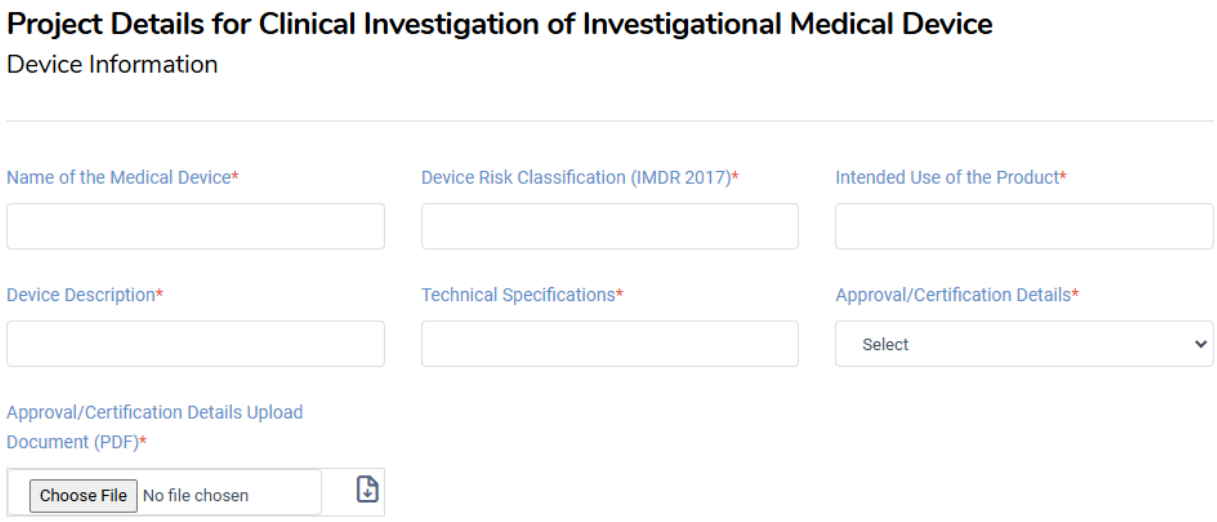
After that you will have to click the **"Save and Submit**" button, but please remember, once submitted, the application cannot be edited. You can click on the **"Previous"** button to edit the application, before clicking on submit.

After submitting, you will receive a confirmation Email from LSSSDC regarding the submission of your application.

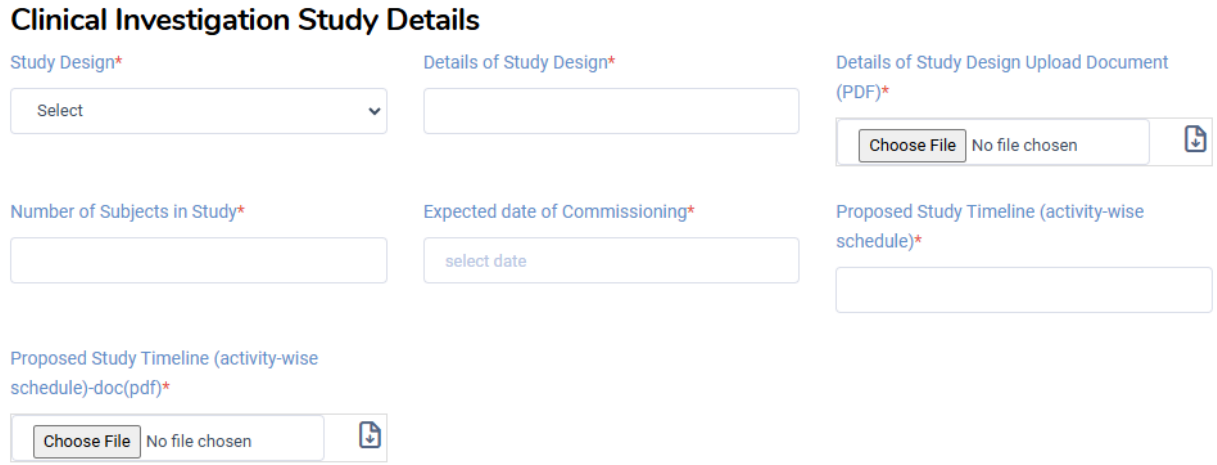
Clinical Investigation of Investigational Medical Device

The **Project Details** for the "Clinical Investigation of Investigational Medical Device" has the following sub-sections:

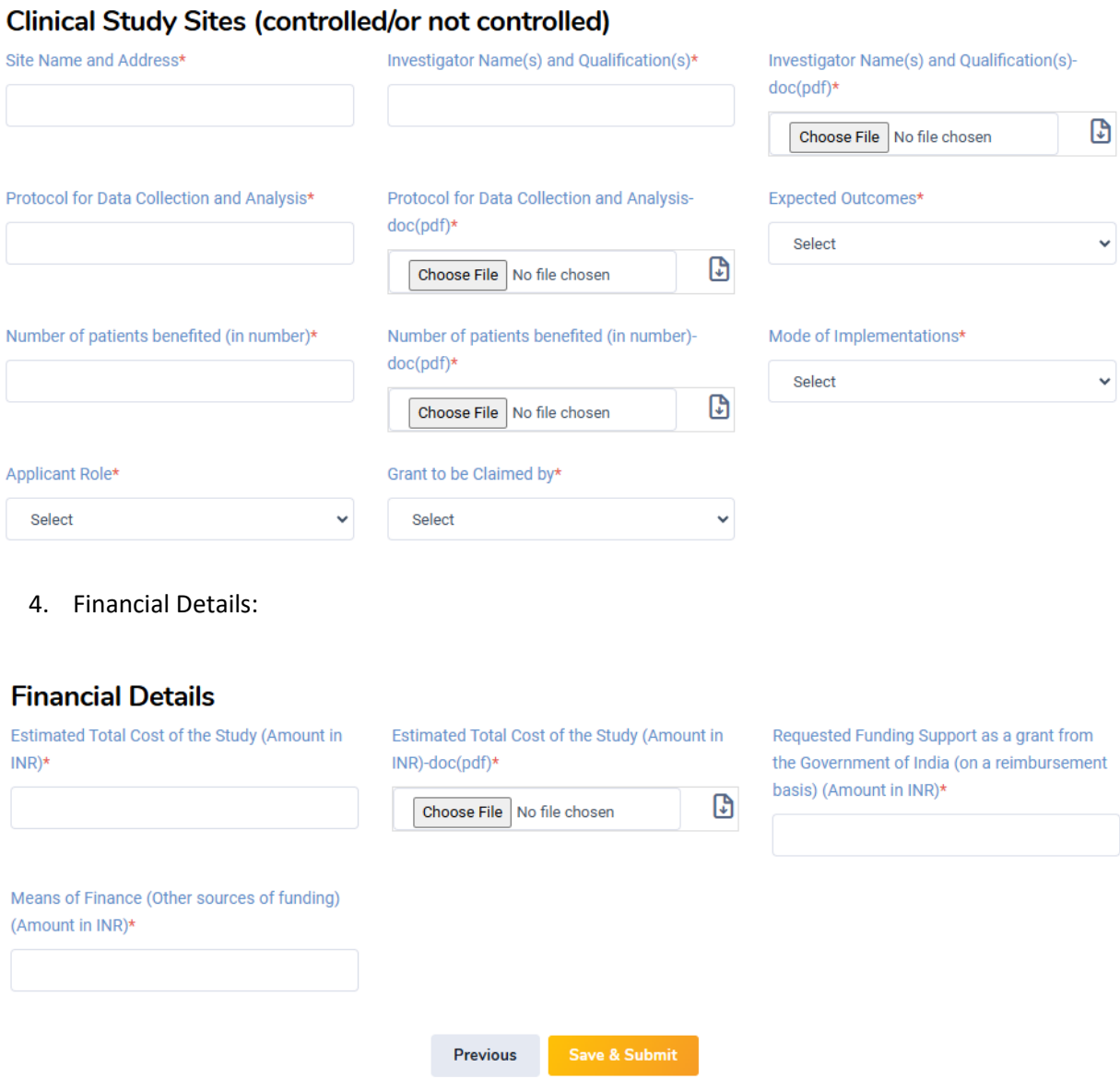
1. Device Information:



2. Clinical Investigation Study Details:



3. Clinical Studies Site (Controlled / or Not Controlled):



4. Financial Details:

After that you will have to click the **"Save and Submit**" button, but please remember, once submitted, the application cannot be edited. You can click on the **"Previous"** button to edit the application, before clicking on submit.

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Clinical Performance Evaluation for New IVDs:

The **Project Details** for the "Clinical Performance Evaluation for New IVDs" has the following sub-sections:

1. Device Information:

Project Details for Clinical Performance Evaluation for New IVDs

Device Information

Name of the In Vitro Diagnostic Medical Device*

Device Risk Classification (IMDR 2017)*

Intended Use of the Product*

Device Description*

Technical Specifications*

2. Clinical Performance Evaluation Study Details:

Clinical Performance Evaluation Study Details

Study Design Details*

Study Design Details Doc(pdf)*

Choose File No file chosen

Sample Size*

Specimen Type (e.g. Human Specimen, Blood etc)*

Expected date of Commissioning*

Proposed Study Timeline (activity-wise schedule)*

Proposed Study Timeline (activity-wise schedule) Upload Document (PDF)*

Choose File No file chosen

3. Study Site Details:

Study Site Details

Laboratory Name and Address*

Key Personnel and Qualifications*

Key Personnel and Qualifications-doc(pdf)*

Choose File No file chosen

Protocol for Data Collection and Analysis*

Protocol for Data Collection and Analysis document file(pdf)*

Choose File No file chosen

Expected Outcomes*

Select

Test License Number (If applicable)*

Mode of Implementation*

Select

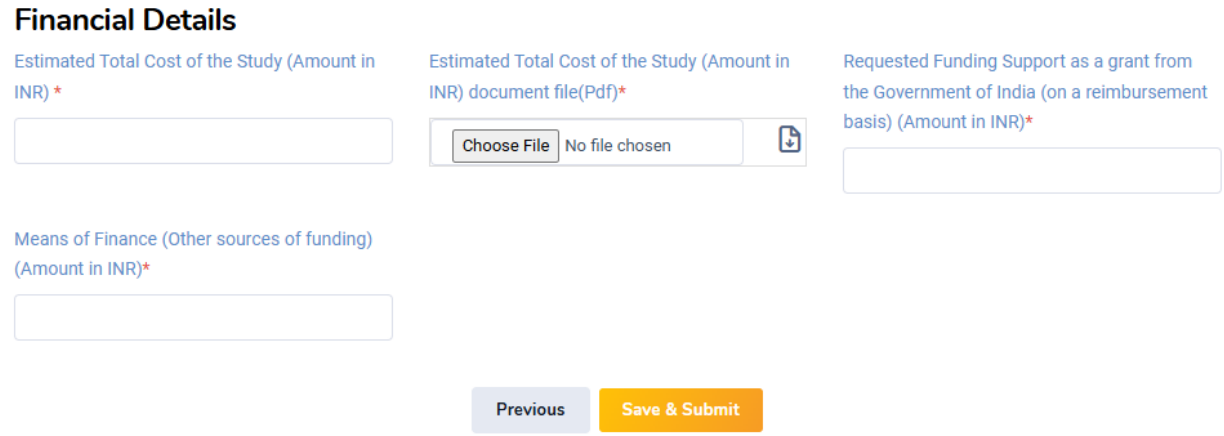
Applicant Role*

Select

Grant to be Claimed by*

Select

4. Financial Details:



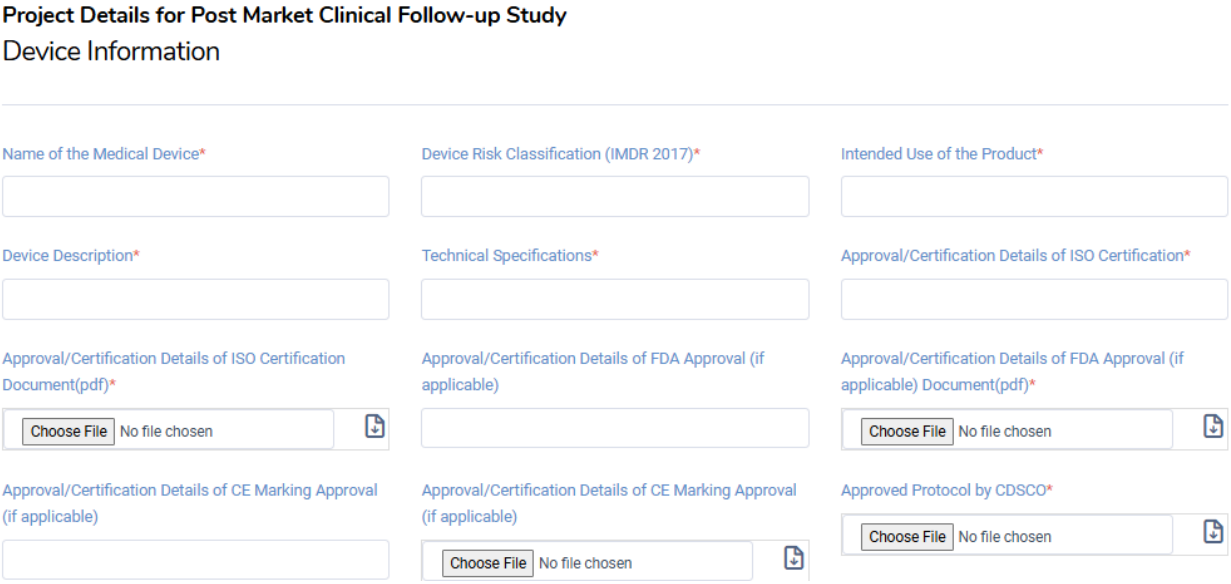
After that you will have to click the **"Save and Submit**" button, but please remember, once submitted, the application cannot be edited. You can click on the **"Previous"** button to edit the application, before clicking on submit.

After submitting, you will receive a confirmation Email from LSSSDC regarding the submission of your application.

Post Market Clinical Follow-up Study

The **Project Details** for the "Post Market Clinical Follow-up Study" has the following sub-sections:

1. Device Information:



2. PMCF Study Details:

PMCF Study Details

Study Design*
Select

Details of Study Design*

Details of Study Design Related document(pdf)*
Choose File No file chosen

Number of Subjects in Study*

Inclusion/ Exclusion Criteria*

Expected date of Commissioning*

Proposed Study Timeline (activity-wise schedule)*

Proposed Study Timeline (activity-wise schedule) document(pdf)*
Choose File No file chosen

3. Clinical Studies Site (Controlled/ or not controlled):

Clinical Study Sites (controlled/or not controlled)

Clinical Site Name and Address*

Investigator Name and Qualifications*

Investigator Name and Qualifications document(pdf)*
Choose File No file chosen

Protocol for Data Collection and Analysis*

Protocol for Data Collection and Analysis document(pdf)*
Choose File No file chosen

Expected Outcomes*
Select

Institutional Ethical Committee Details*

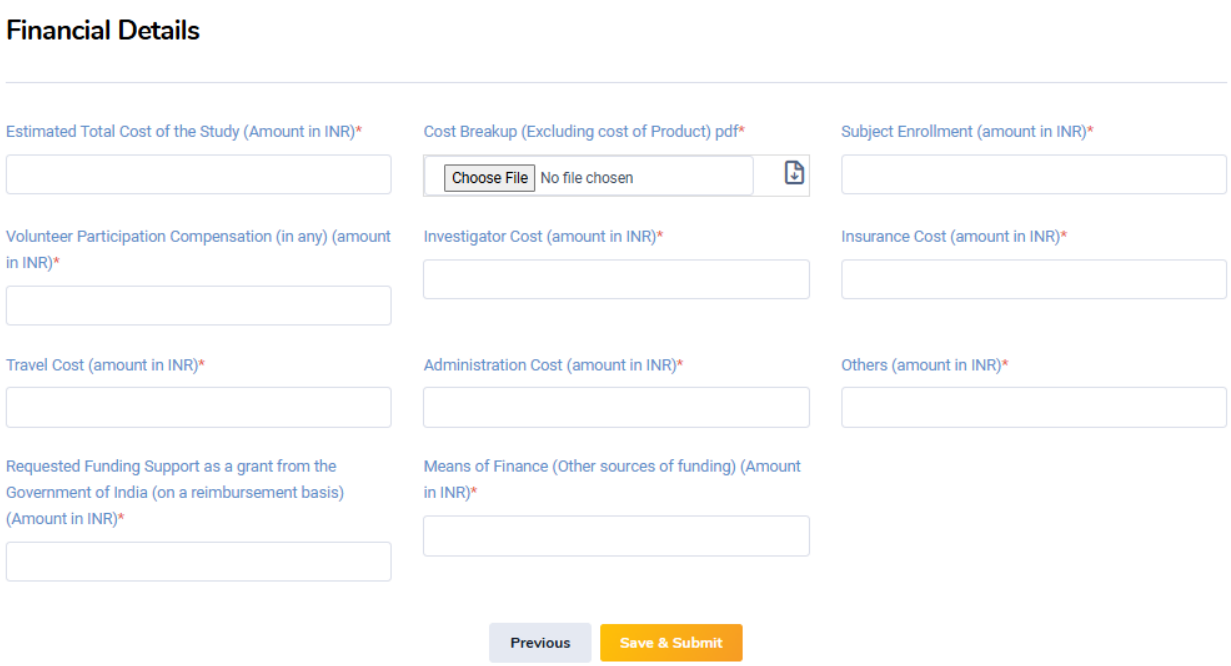
Attach Ethical Committee Clearance Certificate (if Available)
Choose File No file chosen

Mode of Implementation*
Select

Applicant Role*
Sponsor/Product Owner/Manufacturer

Grant to be Claimed by*
Select

4. Financial Details:



After that, you will have to click the **"Save and Submit**" button, but please remember, that once submitted, the application cannot be edited. You can click on the **"Previous"** button to edit the application, before clicking on submit.

After submitting, you will receive a confirmation Email from LSSSDC regarding the submission of your application.