

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:**



Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India

SCHEME FOR STRENGTHENING OF MEDICAL DEVICE INDUSTRY

Last Date Of Receiving The Applications Is Extended Till 31 Jan 2025
11:59 PM

Apply Now

- Marginal Investment Scheme for Reducing Import Dependence →
- Medical Device Clinical Studies Support Scheme →
- Capacity Building and Skill Development for Medical Devices- Component B →

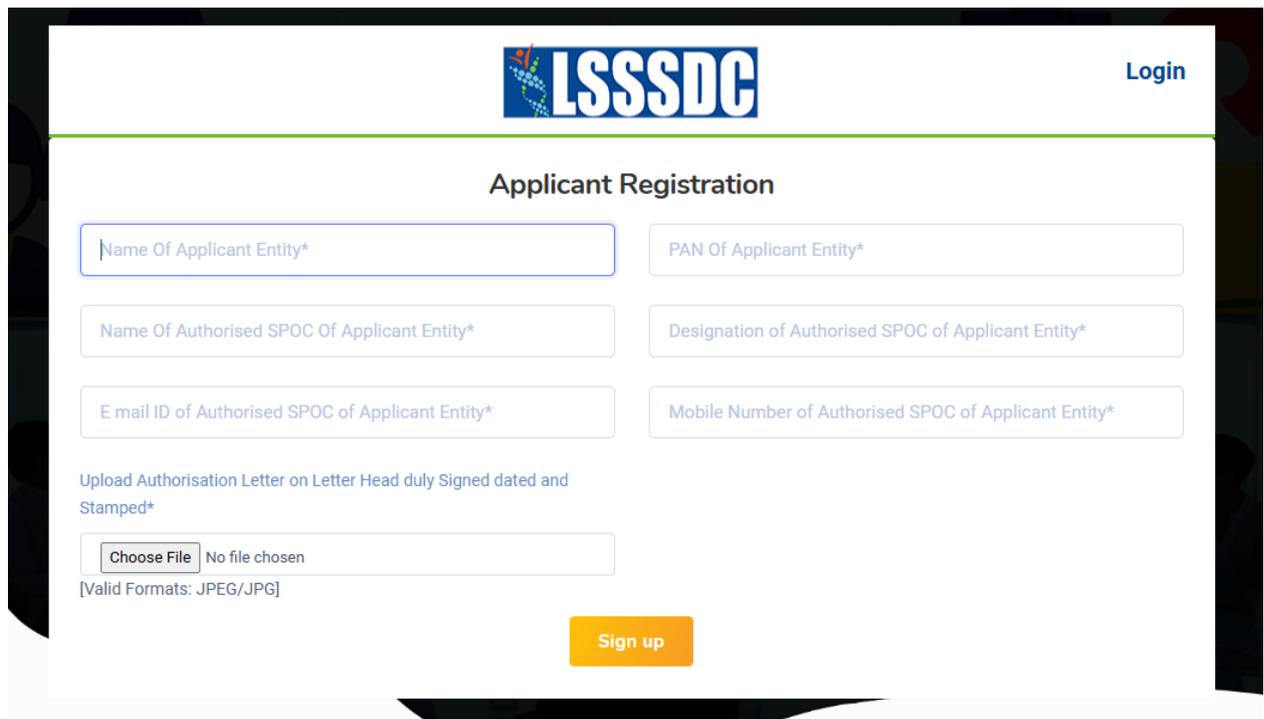
Medical device is a sunrise industry in India, with double digit growth rate. Due to efforts of the government in the last decade in creating a suitable eco-system and incentivizing production of medical devices through PLI scheme, production of technology intensive medical devices such CT scan, MRI, C-arm etc. has started in India. However, as a nascent industry, the sector is facing following KEY challenges.

- Dependence on imports still continues to be about 70%.
- NO incentive of domestic manufacturing of key components/raw materials/accessories etc.
- High cost towards clinical investigations.
- Dearth of available industry ready trained manpower.

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.



The screenshot shows the LSSSDC Applicant Registration form. At the top, there is the LSSSDC logo and a 'Login' link. The form title is 'Applicant Registration'. It contains several input fields: 'Name Of Applicant Entity*', 'PAN Of Applicant Entity*', 'Name Of Authorised SPOC Of Applicant Entity*', 'Designation of Authorised SPOC of Applicant Entity*', 'E mail ID of Authorised SPOC of Applicant Entity*', and 'Mobile Number of Authorised SPOC of Applicant Entity*'. Below these fields is a section for uploading an 'Authorisation Letter on Letter Head duly Signed dated and Stamped*', with a 'Choose File' button and a note that no file has been chosen. The valid formats are listed as JPEG/JPG. At the bottom of the form is a yellow 'Sign up' button.

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:

LSSDC

Applicant Sign In

Login using your username and password.

👤 Enter your email address or username
Required!

🔒 Enter your passcode
Required!

Sign in

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

← → ↻ 🌐 smdi.lssdc.in/applicant/ ☆ 📄 📥 🗑️

LSSDC Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India

Applicant
chitra.kanwar@lssdc.in

Dashboard

Dear LSSDC
Please select scheme and complete your application form for participating for Scheme for Strengthening of Medical Device Industry.

Marginal Investment Scheme for Reducing Import Dependence >>

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.



APPLICATION FORM - Medical Device Clinical Studies Support Scheme

Note: Fields marked with * are required.

1.

2.

3.

REGISTRATION DETAILS BASIC DETAILS PROJECT DETAILS

Applicant Basic Details

<p>Name of Applicant Entity*</p> <input type="text" value="LSSDC"/>	<p>Type of Entity Constitution*</p> <input type="text" value="Select"/>	<p>Organization/Company Premises</p> <p><input type="radio"/> Rented <input type="radio"/> Own <input type="radio"/> Leased <input type="radio"/> Others</p>
<p>Registered Office Details*</p> <div style="border: 1px solid #ccc; height: 40px;"></div>	<p>City*</p> <input type="text"/>	<p>District*</p> <input type="text"/>

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

<p>PIN Code*</p> <input type="text"/>	<p>State*</p> <input type="text"/>	<p>Name of Head of Applicant Entity*</p> <input type="text"/>
<p>Designation of Head of Applicant Entity*</p> <input type="text"/>	<p>E mail ID of Head of Applicant Entity*</p> <input type="text"/>	<p>Mobile Number of Head of Applicant Entity*</p> <input type="text"/>
<p>Name of Authorised SPOC of Applicant Entity*</p> <input type="text" value="Chitra Kanwar"/>	<p>Designation of Authorised SPOC of Applicant Entity*</p> <input type="text" value="Project Coordinator"/>	<p>E Mail Id of Authorised SPOC of Applicant Entity*</p> <input type="text" value="chitra.kanwar@lssdc.in"/>
<p>Mobile Number of Authorised SPOC of Applicant Entity*</p> <input type="text" value="9773982613"/>	<p>Upload Authorisation Letter on Letter Head duly Signed dated and Stamped (jpg, jpeg only)*</p> <input type="button" value="Choose File"/> No file chosen	<p>TAN of Applicant Entity*</p> <input type="text"/>
<p>GST of Applicant Entity (if Available)</p> <input type="text"/>	<p>MSME Status of Entity*</p> <input type="text" value="Select"/>	<p>UDYAM Certificate Number (if Applicable)*</p> <input type="text"/>

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:

1. REGISTRATION DETAILS 2. BASIC DETAILS 3. PROJECT DETAILS

Project Details

Application For*

Select

- Select
- Pre Clinical Studies in Animal Models
- Clinical Investigation of Investigational Medical Device
- Clinical Performance Evaluation for New IVDs
- Post Market Clinical Follow-up Study

Type of Clinical Studies	Previous Experience (Include details of any previous clinical studies conducted by your organization, including outcomes and publications if applicable) *	Tentative Start Date of Project*	Tentative End Date of Project*	Regulatory Approval (if any):List any regulatory approvals received for the device and studies*	EC Approval Status*
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele

Previous
Save & Submit

Pre Clinical Studies in Animal Models



Department of Pharmaceuticals
Ministry of Chemical and Fertilizers
Government of India

Applicant
chitra.kanwar@lssdc.in

1. REGISTRATION DETAILS 2. BASIC DETAILS 3. PROJECT DETAILS

Project Details

Application For*

Pre Clinical Studies in Animal Models

Type of Clinical Studies	Previous Experience (Include details of any previous clinical studies conducted by your organization, including outcomes and publications if applicable) *	Tentative Start Date of Project*	Tentative End Date of Project*	Regulatory Approval (if any):List any regulatory approvals received for the device and studies*	EC Approval Status*
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Sele

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*	Study Design (List of tests Perform) Upload Document (PDF)*	Expected date of Commissioning*
<input type="text" value="Select"/>	<input type="text" value="Choose File No file chosen"/>	<input type="text"/>
Animal Model Testing details*	Animal Model Testing details Upload Document (PDF)*	Proposed Study Timeline (activity-wise schedule)*
<input type="text"/>	<input type="text" value="Choose File No file chosen"/>	<input type="text"/>
Proposed Study Timeline (activity-wise schedule) Upload Document (PDF)*	<input type="text" value="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*
<input type="text"/>	<input type="text"/>	<input type="text"/>
Process Detail of conducting pre-clinical study Upload Document (PDF)*	Expected Outcomes *	Mode of Implementation*
<input type="text" value="Choose File No file chosen"/>	<input type="text" value="Select"/>	<input type="text" value="Select"/>
Applicant Role *	Grant to be Claimed by*	Test License Number (if Available)
<input type="text" value="Select"/>	<input type="text" value="Select"/>	<input type="text"/>

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)*	Requested Funding Support as a grant from the Government of India (on a reimbursement basis) (Amount in INR)*
<input type="text"/>	<input type="text" value="Choose File No file chosen"/>	<input type="text"/>
Means of Finance (Other sources of funding) (Amount in INR)*	<input type="text"/>	

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:

Project Details for Clinical Investigation of Investigational Medical Device

Device Information

Name of the Medical Device*	Device Risk Classification (IMDR 2017)*	Intended Use of the Product*
<input type="text"/>	<input type="text"/>	<input type="text"/>
Device Description*	Technical Specifications*	Approval/Certification Details*
<input type="text"/>	<input type="text"/>	Select 
Approval/Certification Details Upload Document (PDF)*		
<input type="button" value="Choose File"/> No file chosen 		

2. Clinical Investigation Study Details:

Clinical Investigation Study Details

Study Design*	Details of Study Design*	Details of Study Design Upload Document (PDF)*
Select 	<input type="text"/>	<input type="button" value="Choose File"/> No file chosen 
Number of Subjects in Study*	Expected date of Commissioning*	Proposed Study Timeline (activity-wise schedule)*
<input type="text"/>	select date	<input type="text"/>
Proposed Study Timeline (activity-wise schedule)-doc(pdf)*		
<input type="button" value="Choose File"/> No file chosen 		

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

Clinical Study Sites (controlled/or not controlled)

Site Name and Address*

Investigator Name(s) and Qualification(s)*

Investigator Name(s) and Qualification(s)-doc(pdf)*

 No file chosen 

Protocol for Data Collection and Analysis*

Protocol for Data Collection and Analysis-doc(pdf)*

 No file chosen 

Expected Outcomes*

Number of patients benefited (in number)*

Number of patients benefited (in number)-doc(pdf)*

 No file chosen 

Mode of Implementations*

Applicant Role*

Grant to be Claimed by*

4. Financial Details:

Financial Details

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

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

 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

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

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)*

 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)*

 No file chosen 

3. Study Site Details:

Study Site Details

Laboratory Name and Address*

Key Personnel and Qualifications*

Key Personnel and Qualifications-doc(pdf)*

 No file chosen 

Protocol for Data Collection and Analysis*

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

 No file chosen 

Expected Outcomes*

Test License Number (If applicable)*

Mode of Implementation*

Applicant Role*

Grant to be Claimed by*

4. Financial Details:

Financial Details

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

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

 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

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After submitting, you will receive a confirmation Email from LSSDC 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:

Project Details for Post Market Clinical Follow-up Study

Device Information

Name of the Medical Device*

Device Risk Classification (IMDR 2017)*

Intended Use of the Product*

Device Description*

Technical Specifications*

Approval/Certification Details of ISO Certification*

Approval/Certification Details of ISO Certification Document(pdf)*

 No file chosen 

Approval/Certification Details of FDA Approval (if applicable)

Approval/Certification Details of FDA Approval (if applicable) Document(pdf)*

 No file chosen 

Approval/Certification Details of CE Marking Approval (if applicable)

Approval/Certification Details of CE Marking Approval (if applicable)

 No file chosen 

Approved Protocol by CDSCO*

 No file chosen 

2. PMCF Study Details:

PMCF Study Details

Study Design*	Details of Study Design*	Details of Study Design Related document(pdf)*
<input type="text" value="Select"/>	<input type="text"/>	<input type="text" value="Choose File No file chosen"/>
Number of Subjects in Study*	Inclusion/ Exclusion Criteria*	Expected date of Commissioning*
<input type="text"/>	<input type="text"/>	<input type="text"/>
Proposed Study Timeline (activity-wise schedule)*	Proposed Study Timeline (activity-wise schedule) document(pdf)*	
<input type="text"/>	<input type="text" value="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)*
<input type="text"/>	<input type="text"/>	<input type="text" value="Choose File No file chosen"/>
Protocol for Data Collection and Analysis*	Protocol for Data Collection and Analysis document(pdf)*	Expected Outcomes*
<input type="text"/>	<input type="text" value="Choose File No file chosen"/>	<input type="text" value="Select"/>
Institutional Ethical Committee Details*	Attach Ethical Committee Clearance Certificate (if Available)	Mode of Implementation*
<input type="text"/>	<input type="text" value="Choose File No file chosen"/>	<input type="text" value="Select"/>
Applicant Role*	Grant to be Claimed by*	
<input type="text" value="Sponsor/Product Owner/Manufacturer"/>	<input type="text" value="Select"/>	

4. Financial Details:

Financial Details

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

Cost Breakup (Excluding cost of Product) pdf*

 No file chosen 

Subject Enrollment (amount in INR)*

Volunteer Participation Compensation (in any) (amount in INR)*

Investigator Cost (amount in INR)*

Insurance Cost (amount in INR)*

Travel Cost (amount in INR)*

Administration Cost (amount in INR)*

Others (amount in INR)*

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, 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.