



Central Drug Standard Control Organization (CDSCO)

User Manual

For

Post Approval Change (BA/BE Export Division)

Centre for Development of Advanced Computing

(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

Anusandhan Bhawan, C-56/1, Institutional Area, Sector-62, Noida-201307

Phone: 91-120-3063311-14 Website: <http://www.cdac.in>

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Sugam Portal -

Applicant have enter login id and Password then Login

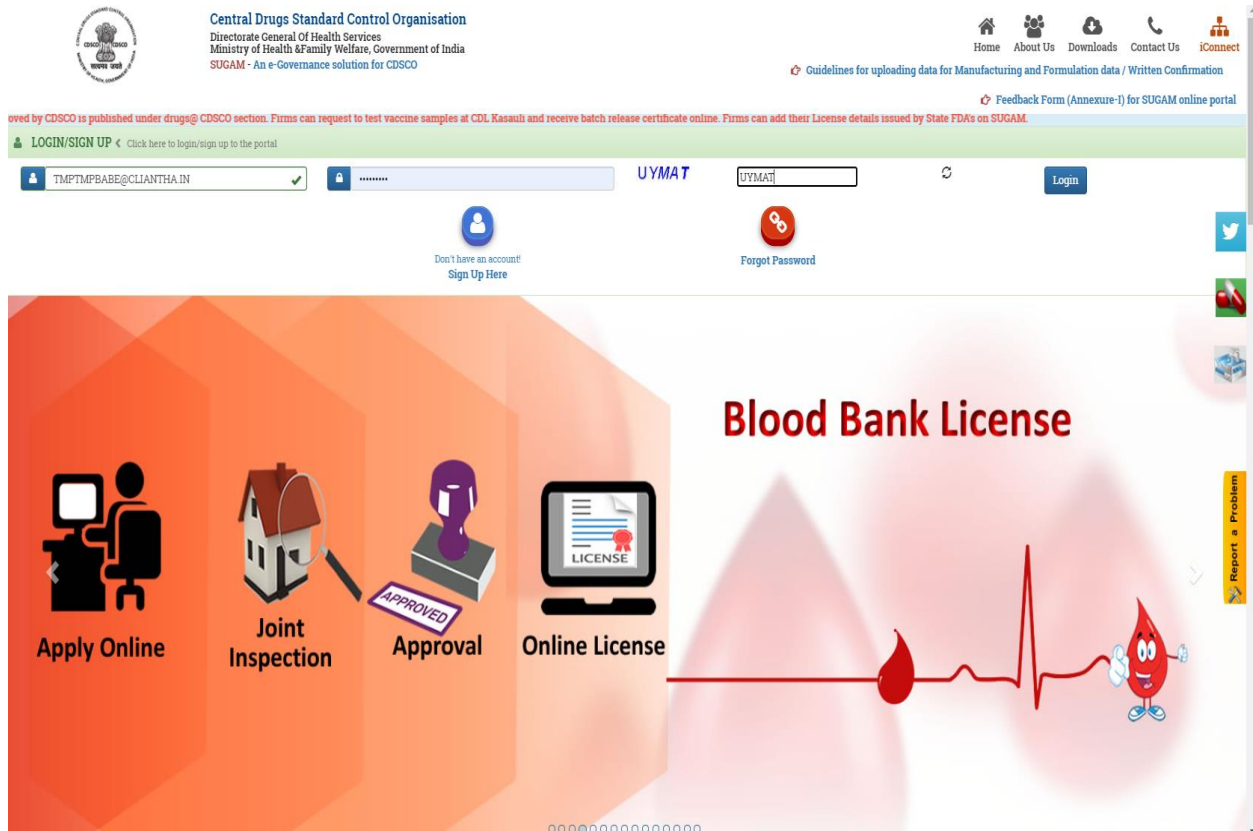
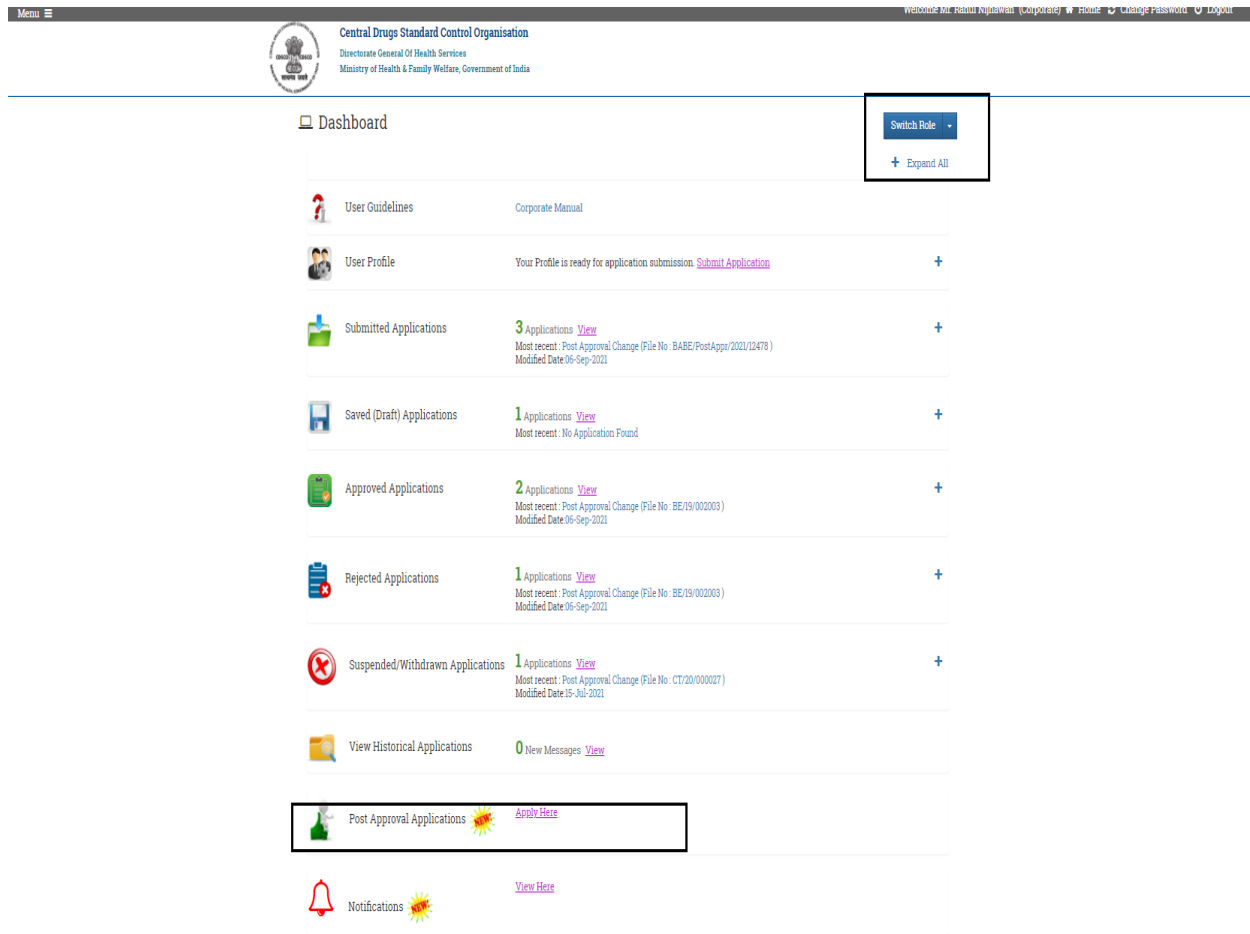


Figure 1: Login Page

Applicant Dashboard -



The screenshot shows the Applicant Dashboard for the Central Drugs Standard Control Organisation. The header includes the organization's name, logo, and user information (Mr. Rajni Kishorani). The dashboard features a sidebar with a 'Dashboard' menu item and a 'Switch Role' button. The main content area displays a list of application categories with their respective counts and 'View' links. A 'Post Approval Applications' tab is highlighted with a red box, and a 'Notifications' bell icon is also visible.

Category	Count	View Link
User Guidelines	Corporate Manual	
User Profile	Your Profile is ready for application submission	Submit Application
Submitted Applications	3 Applications	View
Saved (Draft) Applications	1 Applications	View
Approved Applications	2 Applications	View
Rejected Applications	1 Applications	View
Suspended/Withdrawn Applications	1 Applications	View
View Historical Applications	0 New Messages	View
Post Approval Applications		Apply Here
Notifications		View Here

Figure 2 . Choose Post Approval Application Tab

Post Approval Change

Applicant can choose BABE Export Division by Drop down.



Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Post Approval Change

Access this section to apply For Post Approval Change Request

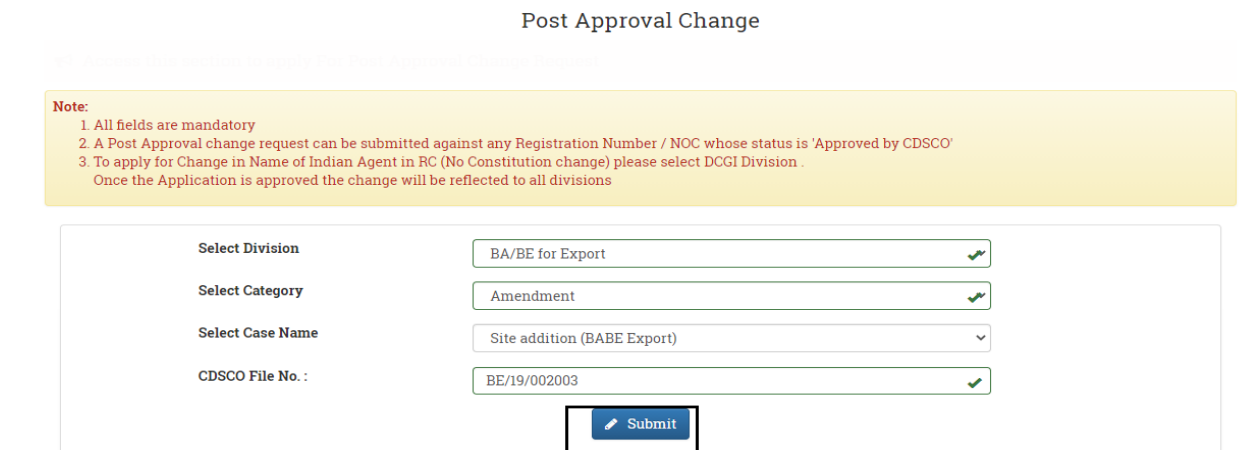
Note:

- 1. All fields are mandatory
- 2. A Post Approval change request can be submitted against any Registration Number / NOC whose status is 'Approved by CDSCO'
- 3. To apply for Change in Name of Indian Agent in RC (No Constitution change) please select DCGI Division .
Once the Application is approved the change will be reflected to all divisions

Select Division

Figure 3

Applicant can choose Select category based on Select Case Name and Enter CDSCO File no.



Post Approval Change

Access this section to apply For Post Approval Change Request

Note:

- 1. All fields are mandatory
- 2. A Post Approval change request can be submitted against any Registration Number / NOC whose status is 'Approved by CDSCO'
- 3. To apply for Change in Name of Indian Agent in RC (No Constitution change) please select DCGI Division .
Once the Application is approved the change will be reflected to all divisions

Select Division

Select Category

Select Case Name

CDSCO File No. :

Figure 4 :Click on Submit

File Related Information

These details are registered which Applicant have submitted at the time of Fresh Application.

Check Old Site



Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Addition of Site involved in Clinical Trial

File Number : BE/19/002003

Site Already Registered

Select	Protocol No.	Version No.	Protocol Date	Amendment No.	Amendment Date
<input type="checkbox"/>	CRL111734	1.0	19-Oct-2019	NA	

Search:

Select	Hospital	No. of Beds	Ethics Committee	Principal Investigator
<input type="checkbox"/>	+ Dr. R M L Institute of Medical Science,Dr RML Institute of Medical Sciences, Lucknow,Uttar Pradesh - 226010(India) Emergency Services : Yes ICU Facility : No	10	RMLIMS Ethics Committee	Name : Dr K K Yadav
<input type="checkbox"/>	+ Dr SR Ramanagoudar MSH and RI Pvt Ltd,Dr S.R. Ramanagoudar MSH and RI Pvt Ltd, Malapur Road, Near VRL Logistics, Dharwad,Karnataka - 580008(India) Emergency Services : Yes ICU Facility : No	65	Ethic Committee of Dr. S.R Ramanagoudar Multispeciality Hospital	Name : Dr Prakash Ramanagoudar
<input type="checkbox"/>	+ Shivam Hospital,C-4, Satyanarayan Society, Gors Kuva, Jashodanagar, Char Rasta, Maninagar(E), ahmedabad,Gujarat - 380008(India) Emergency Services : Yes ICU Facility : No	35	Shivam Ethics Committee	Name : Dr Prakash Kurmi
<input type="checkbox"/>	+ S P Medical College and AG Hospitals,S.P. Medical College and A G Hospitals, Bikaner,Rajasthan - 334001(India) Emergency Services : Yes ICU Facility : No	2088	ETHICS COMMITTEE, S.P.MEDICAL COLLEGE, BIKANER	Name : Dr Sanjay Kochar
<input type="checkbox"/>	+ Sumandeeep Vidhyapeeth and Dhiraj General Hospital,Sumandeeep Vidhyapeeth and Dhiraj General Hospital, PO. Piparia, Ta. Waghodia, Vadodara,Gujarat - 391760(India) Emergency Services : Yes ICU Facility : No	1276	Institutional Ethics Committee, SV	Name : Dr Prasad Muley

← Previous

Figure 5 –if you want to go Previous Page , then click Previous button

Add New Site

BABE Site Details

Hospital *	<input type="text" value="Select"/>
Name of Investigator *	<input type="text" value="Investigator Name"/>
Institutional Ethics Committee (IEC) *	<input type="text" value="Select"/>
No. of Beds in Hospital	<input type="text" value="0"/>
Select IEC Type *	<input type="text" value="Select"/>
Type of Hospital *	<input type="text" value="Select"/>
GCP Trained *	<input type="text" value="Select"/>

Figure 6 . Add New Site

If you want to Change Protocol Details , then click on Particular checkbox.



Central Drugs Standard Control Organisation
 Directorate General of Health Services
 Ministry of Health & Family Welfare, Government of India

Addition of Site involved in Clinical Trial

Site Already Registered

Select	Protocol No.	Version No.	Protocol Date	Amendment No.	Amendment Date
<input checked="" type="checkbox"/>	55	20	07/23/2019	10	09/09/2021

Search:

Select	Hospital	No. of Beds	Ethics Committee	Principal Investigator
<input type="checkbox"/>	Dr. R M L Institute of Medical Science, Dr. RML Institute of Medical Sciences, Lucknow, Uttar Pradesh - 226010(India) Emergency Services : Yes ICU Facility : No	10	FMLIMS Ethics Committee	Name : Dr K K Yadav
<input type="checkbox"/>	Dr SR Ramanagoudar MSH and RI Pvt Ltd, Dr. S.R. Ramanagoudar MSH and RI Pvt Ltd, Malapur Road, Near VRL Logistics, Bharwad, Karnataka - 580008(India) Emergency Services : Yes ICU Facility : No	05	Ethic Committee of Dr. S.R. Ramanagoudar Multispeciality Hospital	Name : Dr. Prakash Ramanagoudar
<input type="checkbox"/>	Shivam Hospital, C-4, Satyanarayan Society, Gors Kuva, Jashodanagar, Char Rasta, Maninagar(E), Ahmedabad, Gujarat - 380008(India) Emergency Services : Yes ICU Facility : No	35	Shivam Ethics Committee	Name : Dr. Prakash Kurmi
<input type="checkbox"/>	S P Medical College and AG Hospitals, S.P. Medical College and A G Hospitals, Bikaner, Rajasthan - 334001(India) Emergency Services : Yes ICU Facility : No	2088	ETHICS COMMITTEE, SPMEDICAL COLLEGE, BIKANER	Name : Dr. Sanjay Kochar
<input type="checkbox"/>	Sumandeep Vidhyapeeth and Dhiraj General Hospital, Sumandeep Vidhyapeeth and Dhiraj General Hospital, PO. Piparia, Ta. Waghodia, Vadodra, Gujarat - 391700(India) Emergency Services : Yes ICU Facility : No	1270	Institutional Ethics Committee, SV	Name : Dr. Prasad Muley

[← Previous](#)

BABE Site Details

Hospital *

Name of Investigator *

Institutional Ethics Committee (IEC) *

No. of Beds in Hospital

Select IEC Type *

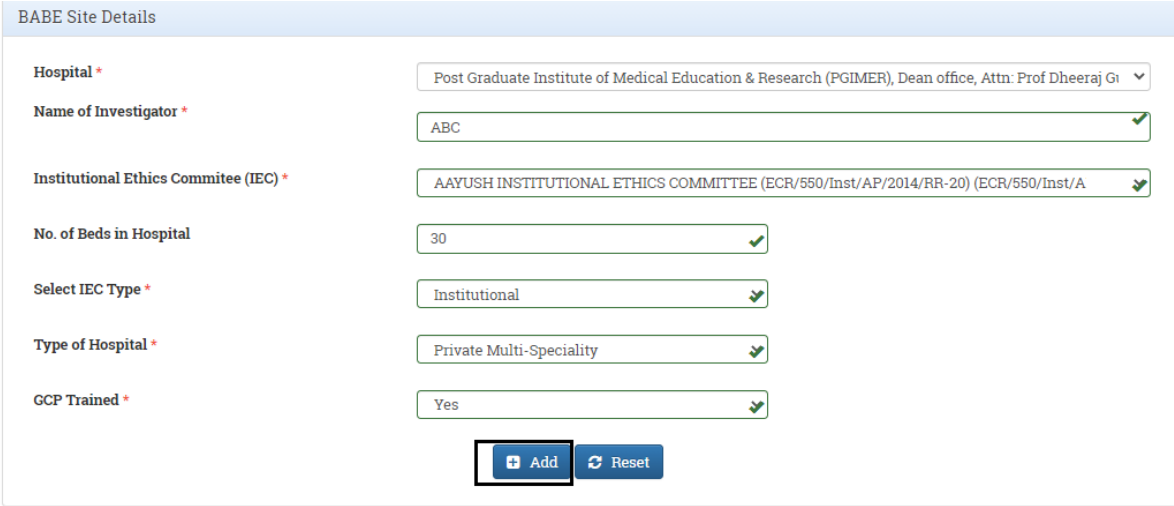
Type of Hospital *

GCP Trained *

[Add](#) [Reset](#)

Figure 7 . Enter new Site

Add New Site



BABE Site Details

Hospital *	Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Attn: Prof Dheeraj G
Name of Investigator *	ABC
Institutional Ethics Committee (IEC) *	AAYUSH INSTITUTIONAL ETHICS COMMITTEE (ECR/550/Inst/AP/2014/RR-20) (ECR/550/Inst/A)
No. of Beds in Hospital	30
Select IEC Type *	Institutional
Type of Hospital *	Private Multi-Speciality
GCP Trained *	Yes

सी डैक CDAC
Designed, Developed and Maintained by C-DAC.

Figure 8 .Add New Site

If you want to add One more Site, you can add any other site,

If you donot get any Site from drop down, then Choose **Other** Option , then Add your own Site. then Click on Next for Checklist Page

BABE Site Details

Hospital *

Name of Investigator *

Institutional Ethics Committee (IEC) *

No. of Beds in Hospital

Select IEC Type *

Type of Hospital *

GCP Trained *

New Sites


Search:

S.No. ↕	Hospital ↕	No. of Beds ↕	Ethics Committee ↕	Principal Investigator ↕	Delete ↕
1	Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Aitn: Prof Dheeraj Gupta, Sector 12, , Chandigarh, Not Available, Chandigarh(India)	30	AAYUSH INSTITUTIONAL ETHICS COMMITTEE	Name : ABC	<input type="button" value="Delete"/>

Figure 9 Click on Next

Confirmation to alert the Box for Checklist Document:

(IEC) *



Are you sure?

You want to proceed to Checklist, as after this you won't be able to modify data

No. of

Figure 10 : POP - UP

Checklist Page :



Central Drugs Standard Control Organisation
Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Upload Essential Documents For Site addition (BABE Export)

Note:

- 1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
- 2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
- 3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard
- 4. Click here to view [Guidelines for PDF documents](#)

<input type="checkbox"/> 1. Covering Letter
<input type="checkbox"/> 2. Undertaking by the Principal Investigator (PI) in original duly signed on a company letterhead as per NDCT, Rules 2019
<input type="checkbox"/> 3. BA/BE Centre approval copy issued by DCG(I), New Delhi, and also furnish the detail of number of beds provided at the Centre (CRO) including ICU beds for effective handling of SAEs in emergency situations
<input type="checkbox"/> 4. Justification & rationale for the proposed change
<input type="checkbox"/> 5. Comparative list of changes in tabular format between existing (approved) and proposed change along with rationale/justification
<input type="checkbox"/> 6. Sponsors Authorization letter duly signed by the Authorized Signatory on company letterhead
<input type="checkbox"/> 7. Copy of registration of Independent/Institutional Ethics Committee (IEC)
<input type="checkbox"/> 8. Undertaking letter from CRO stating that he will provide complete medical care as well as compensation for the injury or Death and statement to this effect should be incorporated in the Informed Consent Form further in case of such injuries or Deaths the details of compensation provided should be intimated to this Directorate as per NDCT, Rules 2019
<input type="checkbox"/> 9. Copy of amended protocol with track change
<input type="checkbox"/> 10. Copy of Ethics Committee approval for the proposed amendment
<input type="checkbox"/> 11. Reason for the delay in conducting the BE study

Submit

Figure 11: Checklist Page

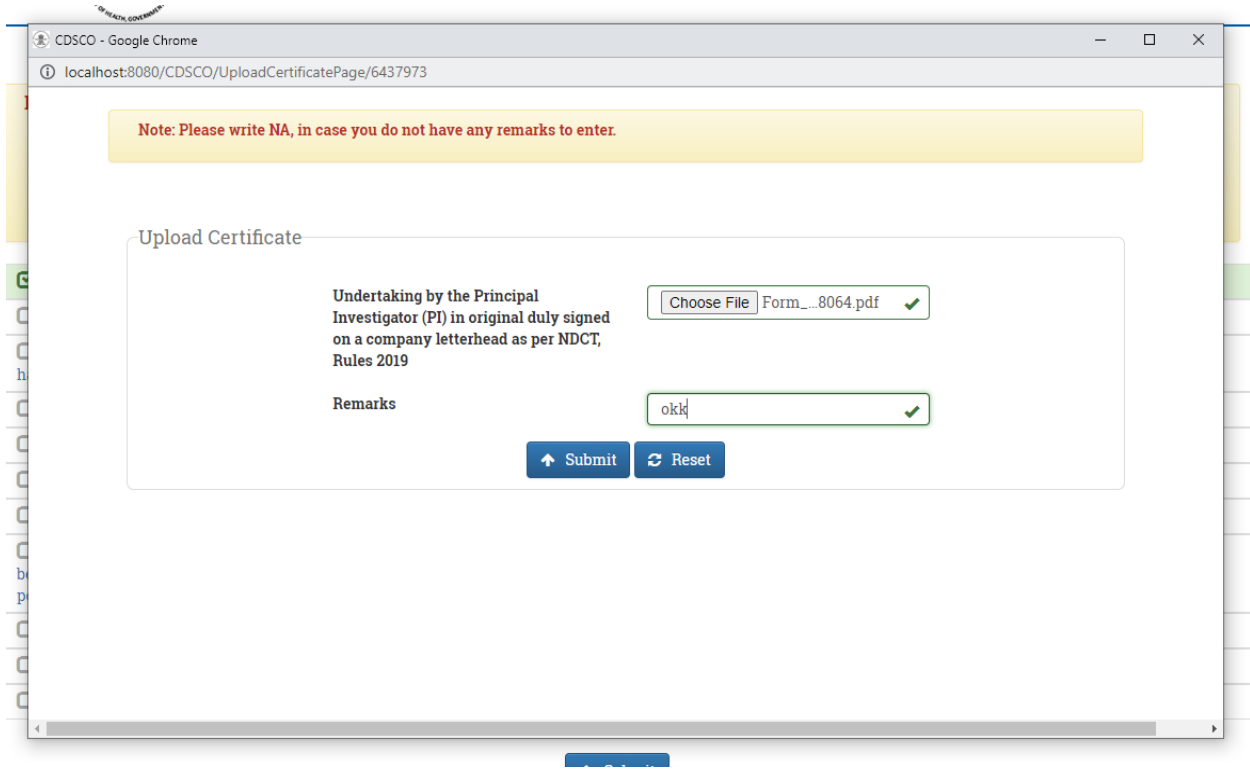


Figure 12: Enter Document, One by One as per the Checklist

Upload Essential Documents For Site addition (BABE Export)

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
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- 1. Covering Letter
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- 5. Comparative list of changes in tabular format between existing (approved) and proposed change along with rationale/justification
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- 9. Copy of amended protocol with track change
- 10. Copy of Ethics Committee approval for the proposed amendment
- 11. Reason for the delay in conducting the BE study

Figure 13 : All Checklist Document Uploaded

Preview Page – It capture your old record and well as new record

NOC Details

File Number: BE/19/002003
Issued On: 04-Dec-2019

Site already registered

Protocol No. ↕	Version No. ↕	Protocol Date ↕	Amendment No. ↕	Amendment Date ↕
CRL111734	1.0	19-Oct-2019	NA	

Search:

Hospital ↕	No. of Beds ↕	Ethics Committee ↕	Principal Investigator ↕
Dr. R M L Institute of Medical Science, Dr RML Institute of Medical Sciences, Lucknow, Uttar Pradesh - 226010 (India) Emergency Services : Yes ICU Facility : No	10	RMLIMS Ethics Committee	Name : Dr K K Yadav
Dr SR Ramanagoudar MSH and RI Pvt Ltd, Dr S R Ramanagoudar MSH and RI Pvt Ltd, Malapur Road, Near VRL Logistics, Dharwad, Karnataka - 590008 (India) Emergency Services : Yes ICU Facility : No	65	Ethic Committee of Dr. S R Ramanagoudar Multispeciality Hospital	Name : Dr Prakash Ramanagoudar
Shivam Hospital, C-4, Satyanarayan Society, Gors Kuva, Jashodanagar, Char Rasta, Maninagar (E), Ahmedabad, Gujarat - 380008 (India) Emergency Services : Yes ICU Facility : No	35	Shivam Ethics Committee	Name : Dr Prakash Kurmi
S P Medical College and AG Hospitals, S.P. Medical College and A G Hospitals, Bikaner, Rajasthan - 334001 (India) Emergency Services : Yes ICU Facility : No	2088	ETHICS COMMITTEE, S.P.MEDICAL COLLEGE, BIKANER	Name : Dr Sanjay Kochar
Sumandeep Vidhyapeeth and Dhiraj General Hospital, Sumandeep Vidhyapeeth and Dhiraj General Hospital, PO. Piparia, Ta. Waghodia, Vadodara, Gujarat - 391760 (India) Emergency Services : Yes ICU Facility : No	1276	Institutional Ethics Committee, SV	Name : Dr Prasad Muley

Proposed BABB site for addition/deletion

Protocol No. ↕	Version No. ↕	Protocol Date ↕	Amendment No. ↕	Amendment Date ↕
55	20	23-Jul-2019	10	09-Sep-2021

Search:

S.No. ↕	Hospital ↕	No. of Beds ↕	Ethics Committee ↕	Principal Investigator ↕
1	Post Graduate Institute of Medical Education & Research (PGIMER), Dean office, Attn: Prof Dheeraj Gupta, Sector 12, Chandigarh, Not Available, Chandigarh (India)	30	AAYUSH INSTITUTIONAL ETHICS COMMITTEE	Name : ABC

Figure 14 : Click on Submit to CDSCO

Finally Submitted :



Central Drugs Standard Control Organisation

Directorate General Of Health Services

Ministry of Health & Family Welfare, Government of India

Your Application has been submitted successfully.
Kindly note your file no. **BABE/PostAppr/2021/12480** for future correspondence.

Figure 15: Successfully Submitted