You can Register Ayurveda Clinical Study / Trial & Survey (human participant) Study in Clinical Trial Registry of India (CTRI) Website (www.ctri.nic.in)

Dr Girish KJ

Professor and Research Co-ordinator

Sri Dharmasthala Manjunatheshwara

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Email: girideepa@yahoo.co.in Mob: 9448646855

Institution: www.sdmcahhassan.org

Personal: www.ayurvedahealthcare.info

What is CTRI?

- The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (http://nims-icmr.nic.in), is a free and online public record system for registration of clinical trials being conducted in India
- Trial registration involves public declaration and identification of trial investigators, sponsors, interventions, patient population etc before the enrollment of the first patient.

What to Register?

- Any researcher who plans to conduct a trial involving human participants, of any intervention such as drugs, surgical procedures, preventive measures, lifestyle modifications, devices, educational or behavioral treatment, rehabilitation strategies as well as trials being conducted in the purview of the Department of AYUSH (http://indianmedicine.nic.in/) is expected to register the trial in the CTRI before enrollment of the first participant.

What to Register?

- Ayurveda Clinical Study / trial of all types
- Survey study involving human participants
  - –May be Postgraduate / doctorate studies
  - –May be sponsored studies

Why register?

- Mandatory from Govt. Guidelines
- CTRI number required while submitting your article in good quality journal
- Patient may refer to the CTRI and may contact you during “Open To recruitment” period.

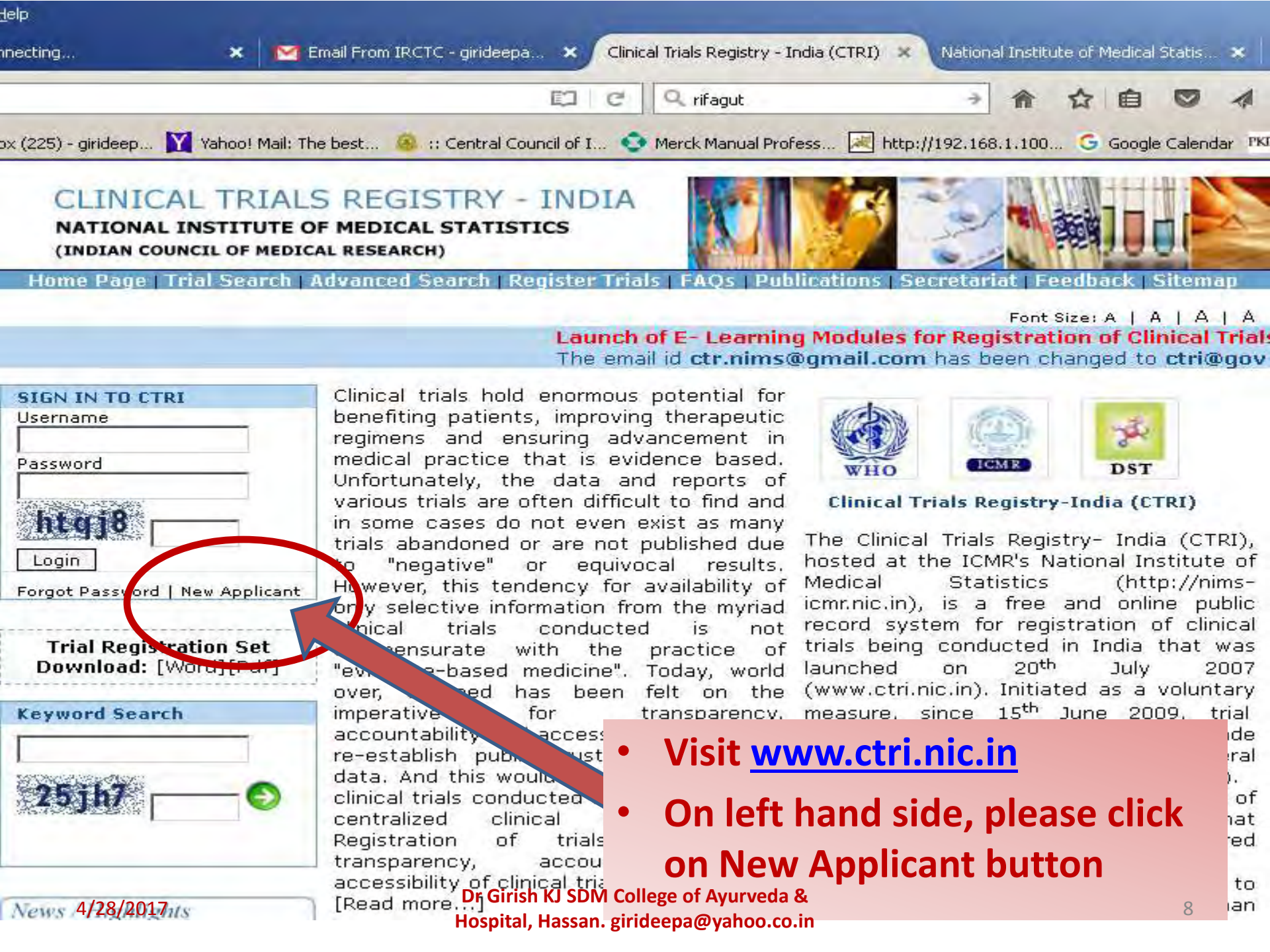
Steps of Registering your Ayurveda Trial

- 1. Open a Free account in CTRI Site
- 2. Fill up CTRI Dataset in the Site
- 3. Do necessary corrections suggested by CTRI
- 4. After obtaining CTRI No. download and save it for future needs.

- **Time Required to get the CTRI No.: Few days to Few Months….**

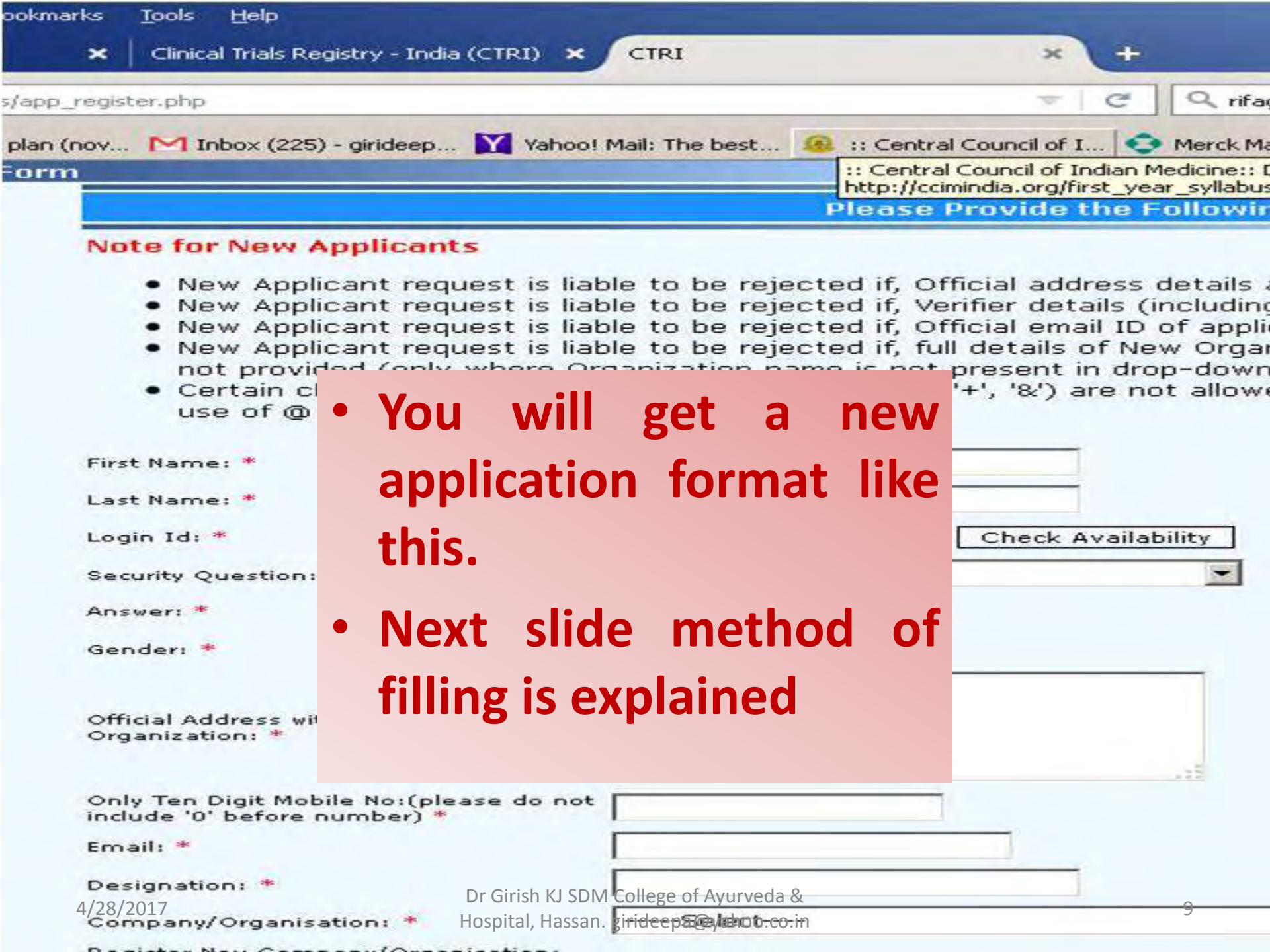
How to Open a Free Account in CTRI Site

- Site : www.ctri.nic.in
- What is required ? –
- Your name, address, your valid email address, name and address of your institution, name and designation, address of your guide / investigators, valid email address and phone number.



- Visit www.ctri.nic.in
- On left hand side, please click on New Applicant button

Dr Girish KJ SDM College of Ayurveda & Hospital, Hassan. girideepa@yahoo.co.in


Clinical Trials Registry - India (CTRI)
CTRI
Note for New Applicants
New Applicant request is liable to be rejected if, Official address details
New Applicant request is liable to be rejected if, Verifier details (including
New Applicant request is liable to be rejected if, Official email ID of appli
New Applicant request is liable to be rejected if, full details of New Orga
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Last Name: *
Login Id: *
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Organization: *
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Company/Organisation: *
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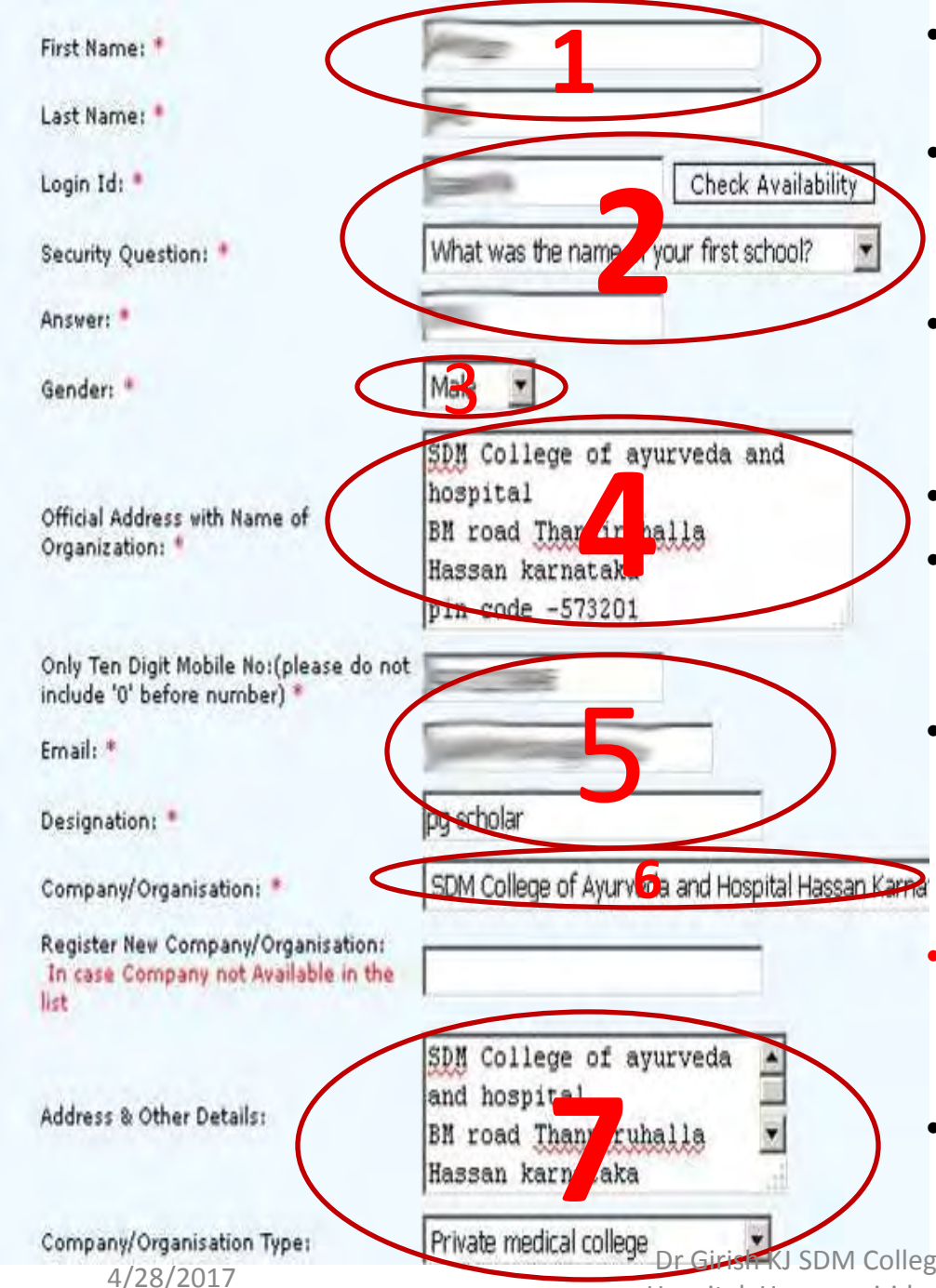
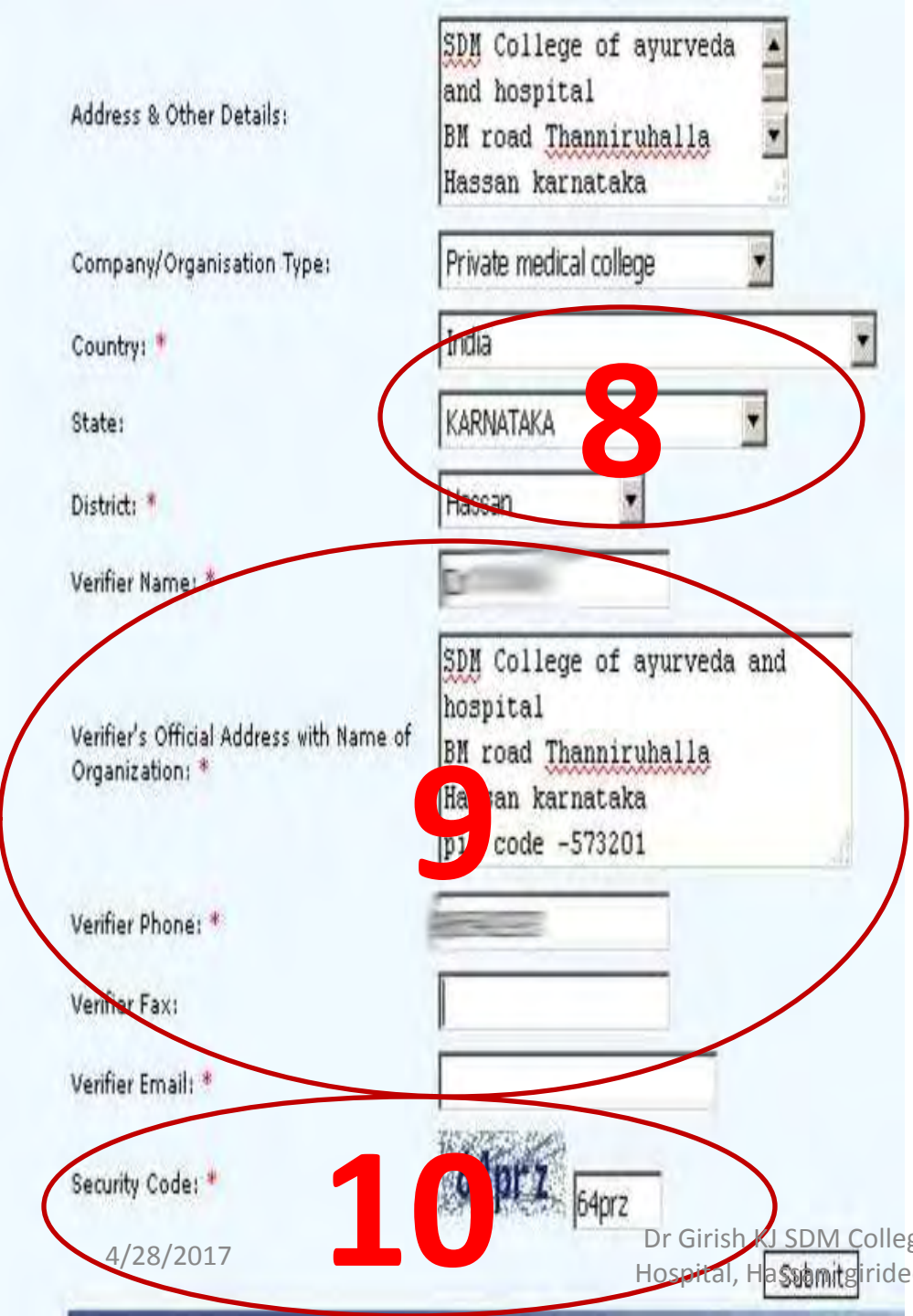
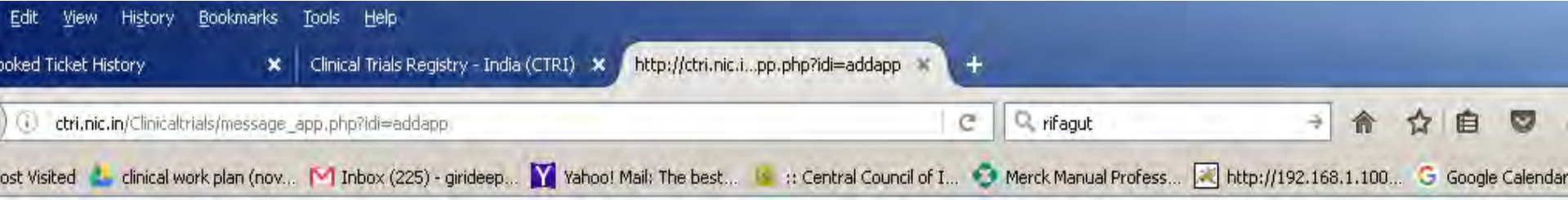
Next slide method of filling is explained



- 1. Please enter you first and last name as in IEC certificate
- 2. type your Login id as you wish without space. Ex: drxyz. And click on Check availability. If available, go ahead.
- Then choose a security question and type answer. **Imp:** Please not this in your diary (hardcopy) for future use
- 3. Choose your gender
- 4. In name and official address, type college address. **Imp: don't use any punctuation mark anywhere.**
- 5. Type you 10 digit mobile number (don't add 0 infront). Type your valid email address and write your designation
- **6. Choose SDMCA Hassan name from drop down list. Don't write anything in register new…**
- 7. Write College address as above in 4. Don't use any punctuation mark. In company type choose private medical college



- 8. Choose India in country, State : Karnataka and District Hassan
- 9. Verifier Name : Type your guides name, Verifier address : College address
- Verifier : Your guide phone and Verifier Email : your guide email address
- 10. Enter security code as it appears on your screen. And Click on submit



Your registration request has been successfully submitted to the CTRI and message sent to the provided email ID. Registration process w
Administrator.

If no communication is received from CTRI within 5 working days, please send a mail to *ctri@gov.in*

Please Click here to go home page

- **You will get screen like this.**
- **So you have to keep checking your email address for login id and password (CTRI will get generate password)**

CTRI Registration Email(Please do not reply this mail)

Inbox ×

adm-ctri@nic.in via yahoo.com

to [redacted]

De[redacted]

Your registration request has been successfully submitted to the CTRI.

Your Login is: [redacted]

Your Password is: [redacted]

Please preserve this email containing USERNAME and system generated PASSWORD for future reference.

Please note that login to CTRI would be activated only after another confirmatory mail is received fr CTRI.

If no confirmatory mail is received from CTRI within 2 working days, please send a mail to ctr.nims@gmail.com

Regards

CTRI Team

REF/[redacted] (H) Inbox x

Clinical Trials Registry - India ctri@gov.in via yahoo.com

to [redacted]

Dear Doctor,

This is in reference to the trial entitled [redacted] submitted to the CTRI for registration

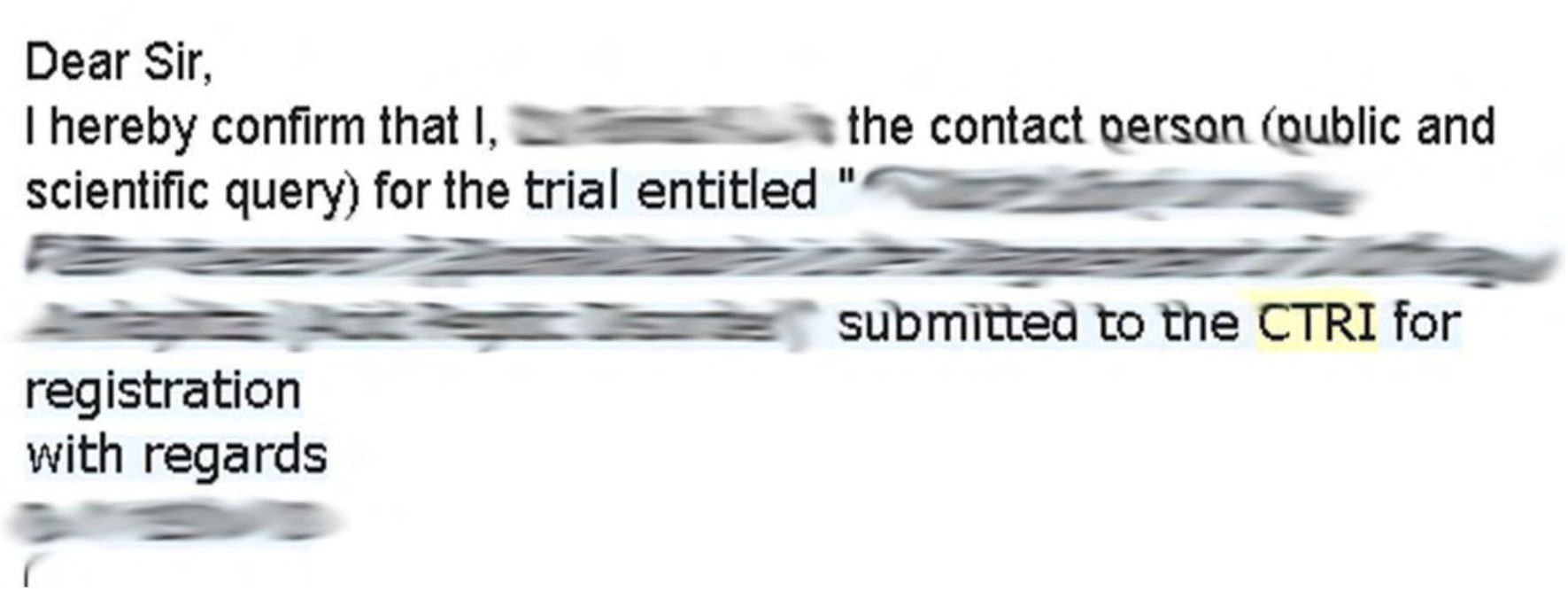
According to the details provided, you are the Contact Person (Scientific Query & Public Query) for the trial

We would appreciate if you could kindly confirm the same as it would help us in trial verification and registration

...

--
Regards

Administrator
Clinical Trials Registry -India (CTRI)
National Institute of Medical Statistics
ICMR
New Delhi


Dear Sir,
I hereby confirm that I, [redacted] the contact person (public and scientific query) for the trial entitled "[redacted]
[redacted] submitted to the CTRI for registration
with regards
[redacted]

- Please inform your guide about the registration as your guide will also receive an email for verification of your details.
- Please ensure that your guide has responded to the verification email from CTRI

Email From IRCTC - girideepa... | Clinical Trials Registry - India (CTRI) | National Institute of Medical Statis...

rifagut

Yahoo! Mail: The best... | :: Central Council of I... | Merck Manual Profess... | http://192.168.1.100... | Google Calendar

CLINICAL TRIALS REGISTRY - INDIA

NATIONAL INSTITUTE OF MEDICAL STATISTICS

Log in with id and password sent to your email by CTRI

Register Trials | FAQs | Publications | Secretariat | Feedback | Sitemap

Font Size: A | A | A | A

Launch of E- Learning Modules for Registration of Clinical Trials

The email id **ctr.nims@gmail.com** has been changed to **ctri@gov.**

SIGN IN TO CT

Username

Password

htqj8

Login

Forgot Password | New Applicant

Trial Registration Set Download: [Word][Pdf]

Keyword Search

25jh7

News / Highlights

ical trials hold enormous potential for benefiting patients, improving therapeutic regimens and ensuring advancement in medical practice that is evidence based. Unfortunately, the data and reports of various trials are often difficult to find and in some cases do not even exist as many trials abandoned or are not published due to "negative" or equivocal results. However, this tendency for availability of only selective information from the myriad clinical trials conducted is not commensurate with the practice of "evidence-based medicine". Today, world over, a need has been felt on the imperative for transparency, accountability and accessibility in order to re-establish public trust in clinical trial data. And this would be feasible only if all clinical trials conducted are registered in a centralized clinical trials registry. Registration of trials will ensure transparency, accountability and accessibility of clinical trials. [Read more.]

WHO | ICMR | DST

Clinical Trials Registry-India (CTRI)

The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (http://nims-icmr.nic.in), is a free and online public record system for registration of clinical trials being conducted in India that was launched on 20th July 2007 (www.ctri.nic.in). Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI) (www.cdsco.nic.in). Moreover, Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication[1, 2].

Today, any researcher who plans to conduct a trial involving human

You may download the dataset from..

- **Original from CTRI Site**
- http://ctri.nic.in/Clinicaltrials/CTRI_Dataset_and_Description.pdf
- And
- **Modified from following link**
- https://www.ayurvedahealthcare.info/ctri-dataset

Clinical Trials Registry - India
NATIONAL INSTITUTE OF MEDICAL STATISTICS
(Indian Council of Medical Research)

Welcome: [redacted] [SDM College of Ayurveda and Hospital Hassan Karnataka 30/03/2016 India]

Main Page | Ch

Trial Clarification/Modification | Registered Trials | General Query | Edit Profile

Total Trials	**0**
Under Entry Stage	0
Under Review Stage	0
Registered Trials	0
Terminated/Suspended Trials	0

Click on Add New Trial Button

Add New Trial

Trials Under Entry/ Review

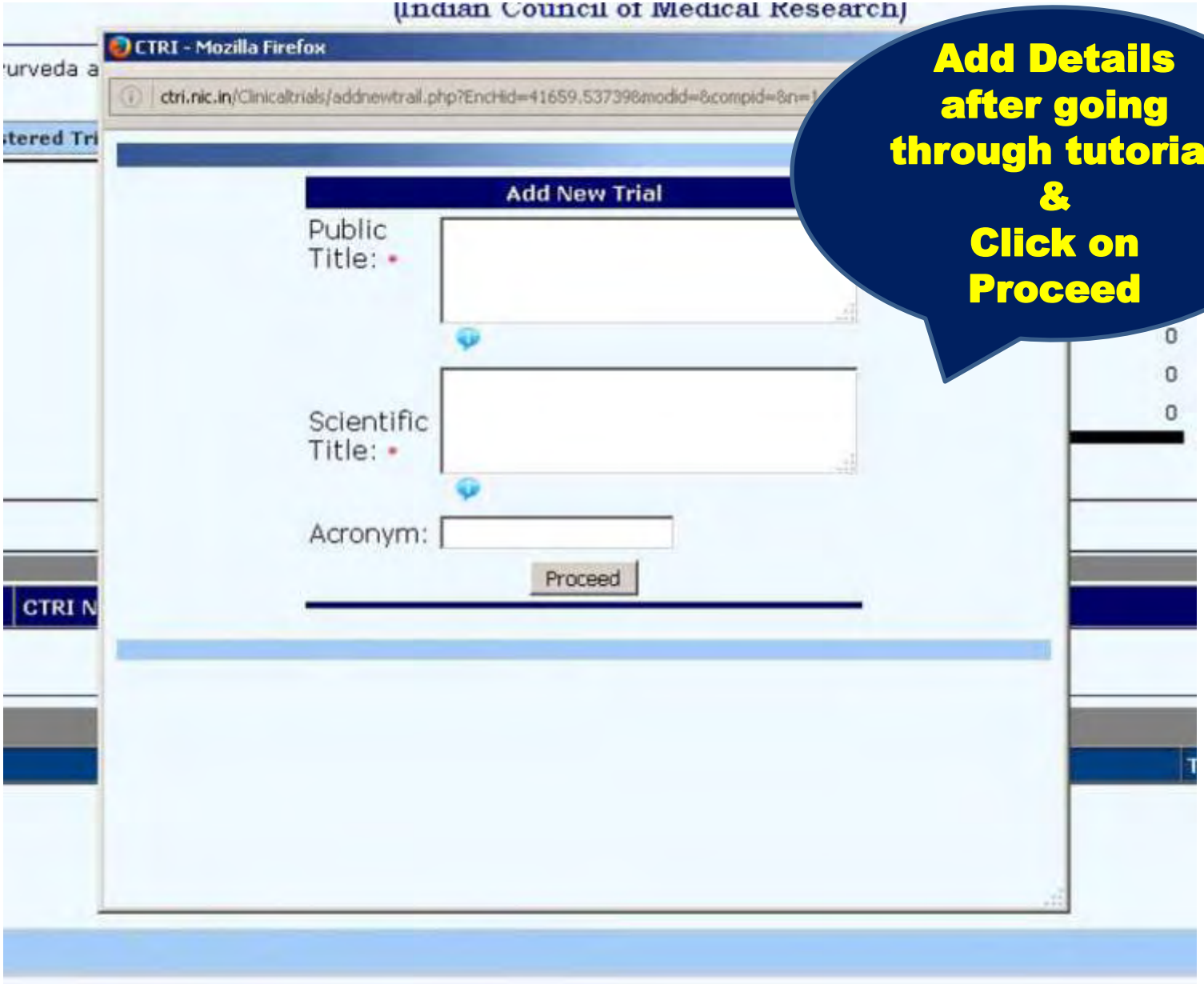
S.No.	Reference No	CTRI No	Scientific Title	Acronym	Secondary ID	V

Trials sent back after review by CTRI

CTRI No.	REF No.	SENT BACK ON	PROTOCOL No.	TRI

CTRI Field	Description	
Public title of study	Title intended for the lay public in easily understood language. **Example:** A clinical trial to study the effects of two drugs, ramipril and candesartan in patients with high blood pressure and type 2 diabetes mellitus.	
Scientific title of study Acronym, if any	Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. **Example:** A randomized double-blind placebo controlled crossover clinical trial to compare the safety	

Read this carefully and after going through tutorial Public and scientific titles may vary



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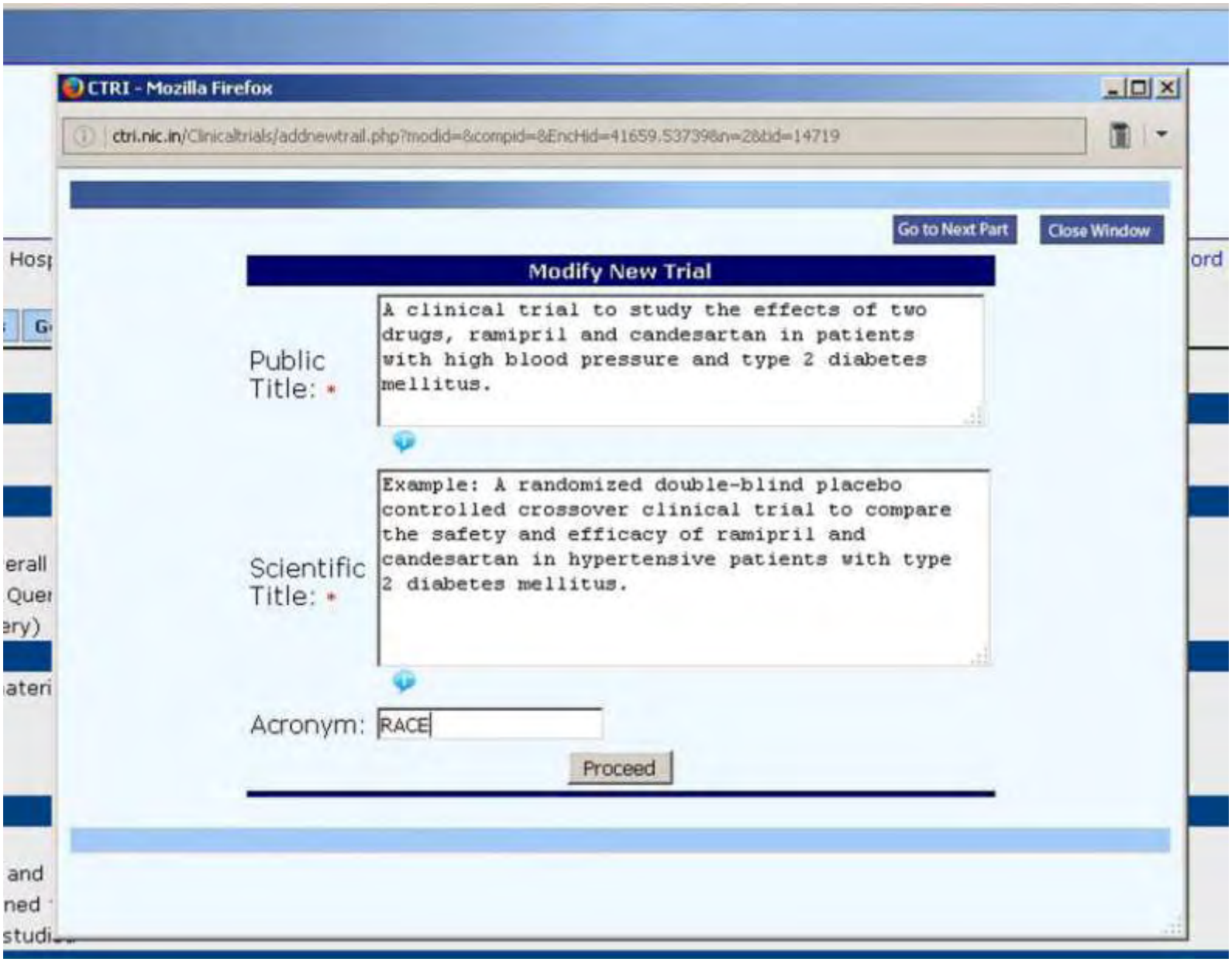
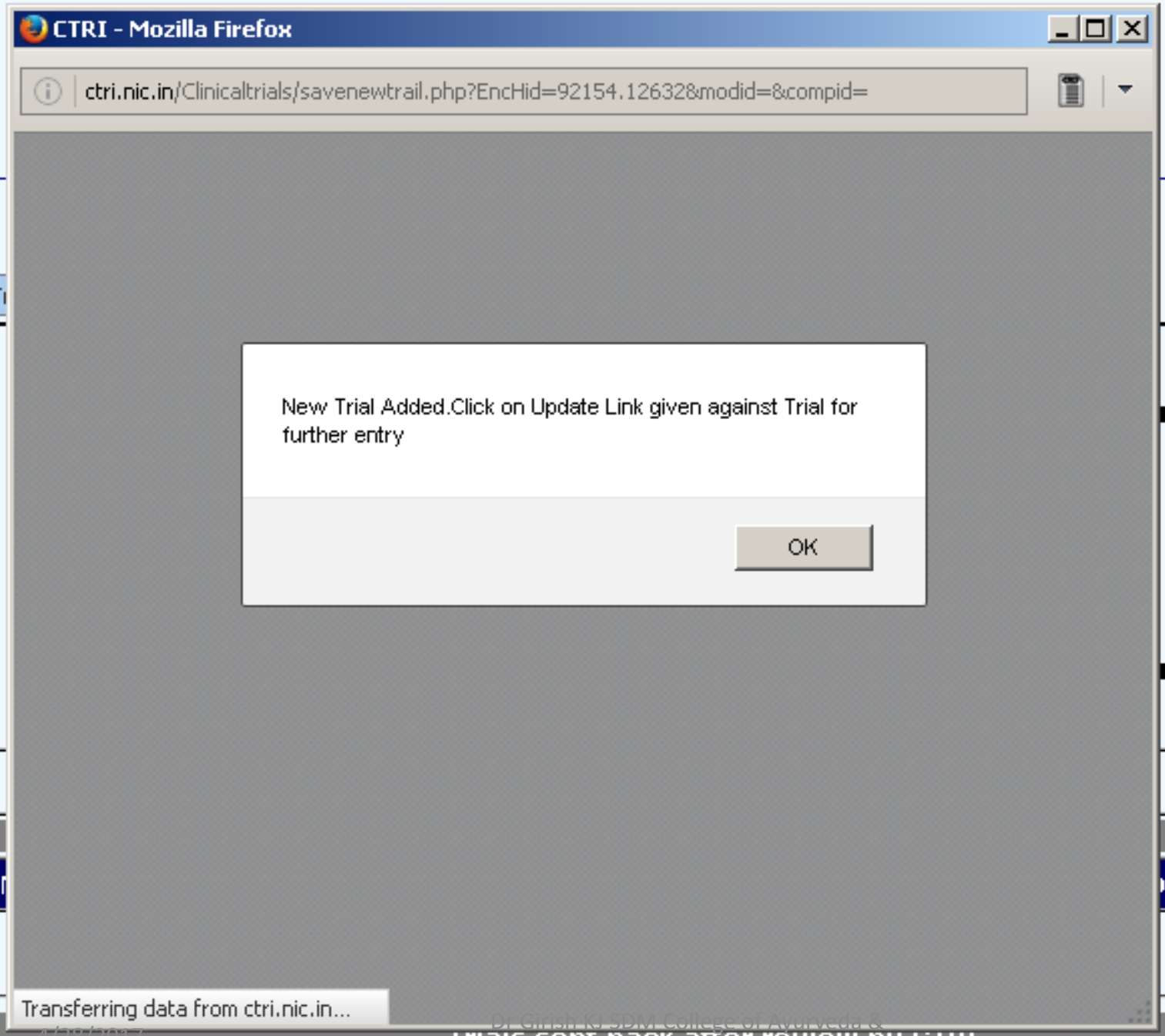

CTRI - Mozilla Firefox
ctri.nic.in/Clinicaltrials/addnewtrail.php?modid=&compid=&EncHid=41659.53739&n=28&bid=14719
Go to Next Part
Close Window
Modify New Trial
Public Title: *
A clinical trial to study the effects of two drugs, ramipril and candesartan in patients with high blood pressure and type 2 diabetes mellitus.
Scientific Title: *
Example: A randomized double-blind placebo controlled crossover clinical trial to compare the safety and efficacy of ramipril and candesartan in hypertensive patients with type 2 diabetes mellitus.
Acronym:
RACE
Proceed


CTRI - Mozilla Firefox
ctri.nic.in/Clinicaltrials/savenewtrail.php?EncHid=92154.12632&modid=8&compid=
New Trial Added.Click on Update Link given against Trial for further entry
OK
Transferring data from ctri.nic.in...

- Refresh Page by pressing F5 key

Total Trials	**1**
Under Entry Stage	1
Under Review Stage	
Registered Trials	0
Terminated/Suspended Trials	0

Click on Update Button

Add New Trial

Trials Under Entry/ Review

	Scientific Title	Acronym	Secondary ID	View Details	Select
	abcdefgh	ABCD-GH		Full Details	Update || Delete

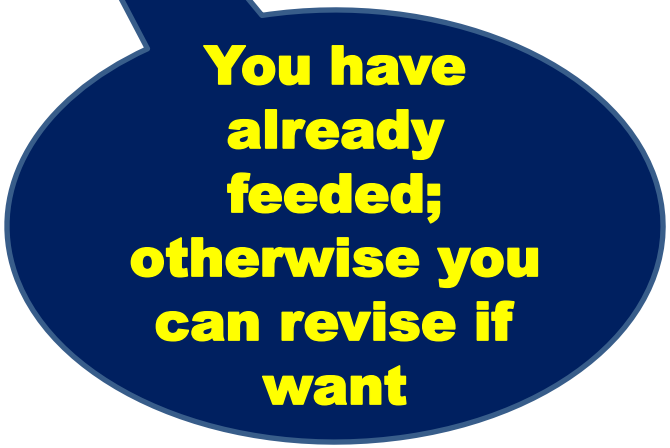
Trials sent back after review by CTRI

	REF No.	SENT BACK ON	PROTOCOL No.	TRIAL TYPE	CLARIFICATION

Part 1		**Click**
1	Public title of study	
2	Scientific title of study	
Part 2		**Click**
1	Secondary IDs	
2	Principal Investigator or overall Trial Coordinator (multi-center study) Details	
3	Contact person (Scientific Query)	
4	Contact person (Public Query)	
Part 3		**Click**
1	Source/s of monetary or material support	
2	Primary sponsor	
3	Secondary Sponsor	
4	Countries of recruitment	
Part 4		**Click**
1	Site/s of study	
2	Name of Ethics Committee and approval status	
3	Regulatory clearance obtained from DCGI	
4	Health condition/problems studied	
Part 5		**Click**
1	Study Type	
Part 6		**Click**
1	Intervention and comparator agent	
2	Inclusion & Exclusion Criteria	
3	Method of generating randomization sequence	
4	Method of allocation concealment	
5	Blinding/masking	
Part 7		**Click**
1	Primary outcome/s	

Scientific Name of Trial: abcdefgh-[ABC

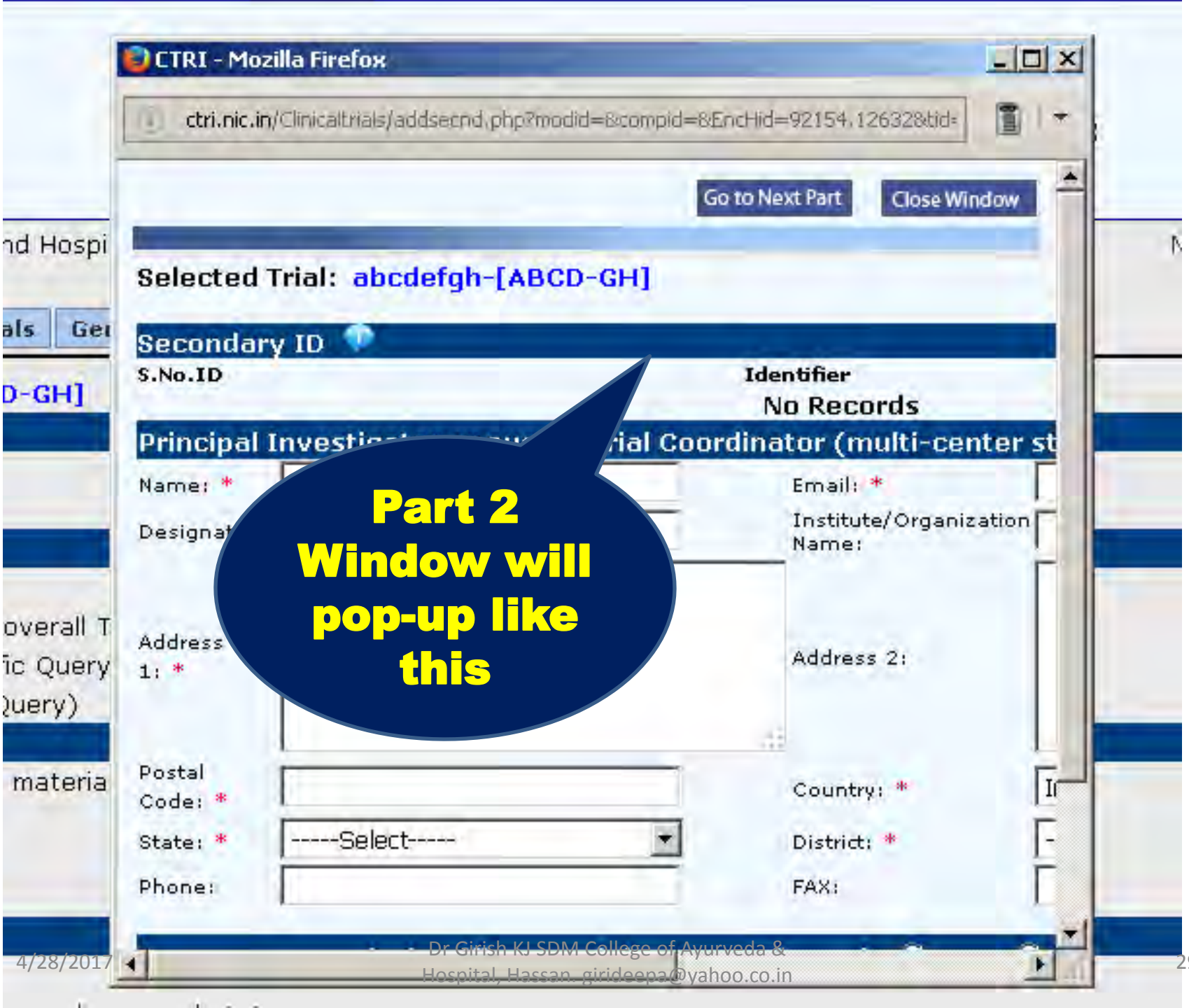
Part 1	
1	Public title of study
2	Scientific title of study



Click on Proceed to Save And to Part 2 PI click on Go to Next Part

2	Scientific title of study
Part 2	
1	Secondary IDs
2	Principal Investigator or overall Trial Coordinator (multi-center study) Details
3	Contact person (Scientific Query)
4	Contact person (Public Query)

Part 2 Click on the Click button right side of Part 2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ctri.nic.in/Clinicaltrials/addsecnd.php?modid=&compid=&EncHid=92154,12632&tid=
Go to Next Part
Close Window
Selected Trial: abcdefgh-[ABCD-GH]
Secondary ID
S.No.ID
Identifier
No Records
Name: *
Email: *
Institute/Organization Name:
Address 1: *
Address 2:
Postal Code: *
Country: *
State: *
-----Select-----
District: *
Phone:
FAX:
Part 2 Window will pop-up like this

Principal Investigator's name and address	Details should include name, official address, affiliation and designation, contact telephone and fax numbers and email ID. For a multi-center study, enter the contact information for the lead Principal Investigator (PI) or overall Trial Coordinator. Designated person must be from India (for trials being conducted in India). This is not a mandatory field.	Dr _____ _____ Dept Of _____ Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India +91 _____ Email : _____

PI details as this. Give your email id as all communications will be sent

Contact person (Scientific Query)	**PG Thesis Registration** **Trials being conducted as part of PG thesis should mention both student's as well as Guide's name and full official address, including department. Co-guide name may also be included, if desired).** **Names should be included in Contact Person details after mutual agreement on division of responsibilities.** **Verification is sought by email from all trial Contact Persons, except the trial Registrant.** Details should include name, official address, affiliation	1. Dr _____ _____ Dept Of _____ Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India +91 _____ email _____ 2. Dr _____ _____ Dept Of _____ Sri Dharmasth Manjunatheshwara College of veda and Hospital BM Road T ruhalla Hassan 573201 Kar India +91 _____ email :

PG Thesis, please give your guides details (give your guide email address

Contact person (Public Query)	Details should include name, official address, affiliation and designation, email address, telephone number, Fax No and postal address of the contact who will respond to general queries, including information about current recruitment status. This may or may not be the same as the contact person for scientific queries.	Dr _____ _____ Dept Of _____ Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India +91 _____ Email: _____

PG Thesis, please give your guides details (give your guide email address

No Records

Principal Investigator or overall Trial Coordinator (multi-center study) Details

Name: *	DR XYZ	Email: *	abcd@abcd.com
Designation:	R DEPARTMENT OF KAYACHIKITSA	Institute/Organization Name:	SRI DHARMASTHALA MANJUNATHE
Address 1: *	SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL BM ROAD THANNIRUHALLA HASSAN	Address 2:	
Postal Code: *	573201	Country: *	India
State: *	KARNATAKA	District: *	Hassan
Phone:	08172256460	FAX:	

Contact Person (Scientific Query) (same as above?) ○ Yes ◉ No

Name: *	Dr Girish KJ	Email: *	xyz@xyz.com
Designation:	PROFESSOR DEPARTMENT OF KAY.	Institute/Organization Name:	LEGE OF AYURVEDA AND HOSPITAL
Address 1: *	SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL BM ROAD THANNIRUHALLA HASSAN	Address 2:	
Postal Code: *	573201	Country: *	India
State:	KARNATAKA	District:	Hassan
Phone:	08172256460	FAX:	

Contact Person (Public Query) (If same as above?) ○ Yes ◉ No

Name: *	Dr Girish KJ	Email: *	
Designation:		Institute/Orga Name:	

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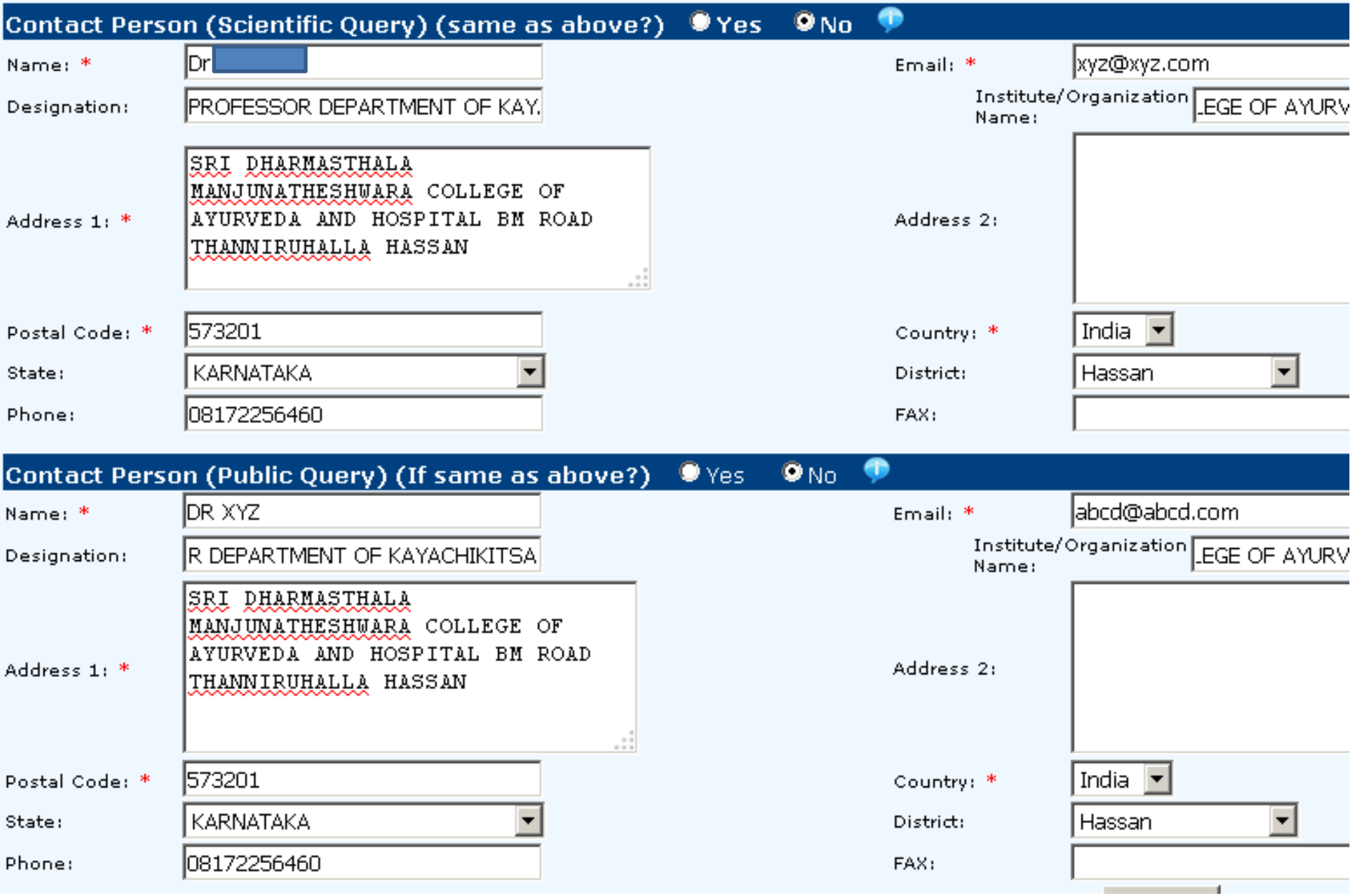
Contact Person (Scientific Query) (same as above?) Yes No
Name: * Dr
Email: * xyz@xyz.com
Designation: PROFESSOR DEPARTMENT OF KAY.
Institute/Organization Name: .EGE OF AYURV
Address 1: * SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL BM ROAD THANNIRUHALLA HASSAN
Address 2:
Postal Code: * 573201
Country: * India
State: KARNATAKA
District: Hassan
Phone: 08172256460
FAX:
Contact Person (Public Query) (If same as above?) Yes No
Name: * DR XYZ
Email: * abcd@abcd.com
Designation: R DEPARTMENT OF KAYACHIKITSA
Institute/Organization Name: .EGE OF AYURV
Address 1: * SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL BM ROAD THANNIRUHALLA HASSAN
Address 2:
Postal Code: * 573201
Country: * India
State: KARNATAKA
District: Hassan
Phone: 08172256460
FAX:

Part 3	
1	Source/s of monetary or material support
2	Primary sponsor
3	Secondary Sponsor
4	Countries of recruitment

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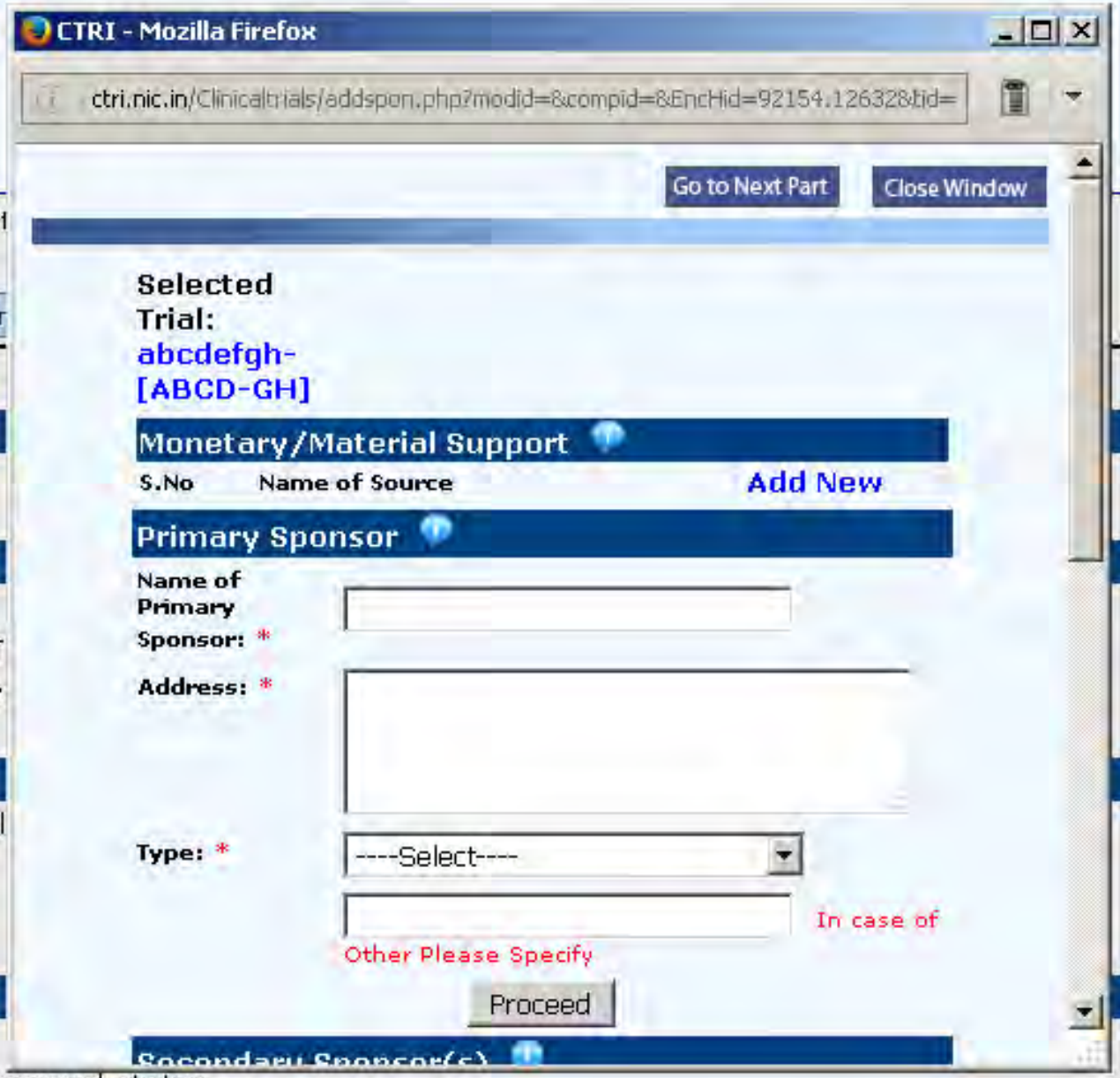
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ctri.nic.in/Clinicaltrials/addspon.php?modid=&compid=&EncHid=92154.12632&tid=
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Monetary/Material Support
S.No
Name of Source
Add New
Primary Sponsor
Name of Primary Sponsor: *
Address: *
Type: *
----Select----
In case of
Other Please Specify
Proceed

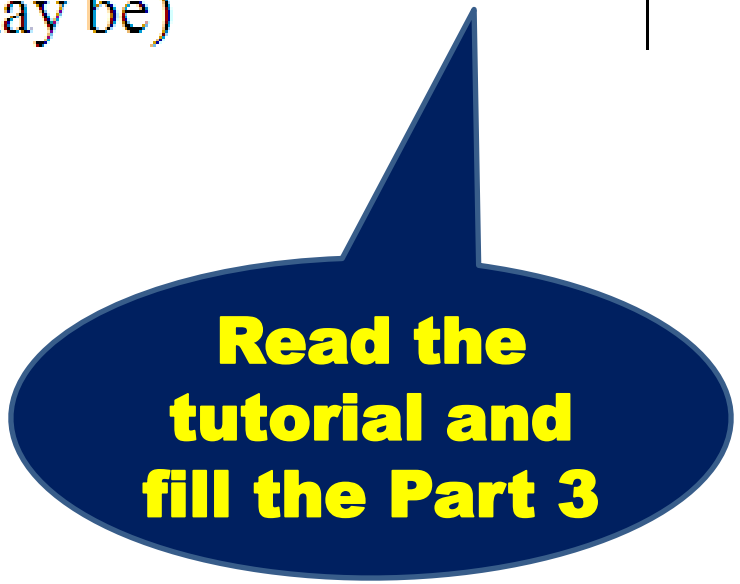
Source/s of monetary or material support	Major source/s of monetary or material or infrastructural support for the trial (e.g., funding agency, foundation, company, hospital, university, etc).	Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India College Phone: _____ Email: _____

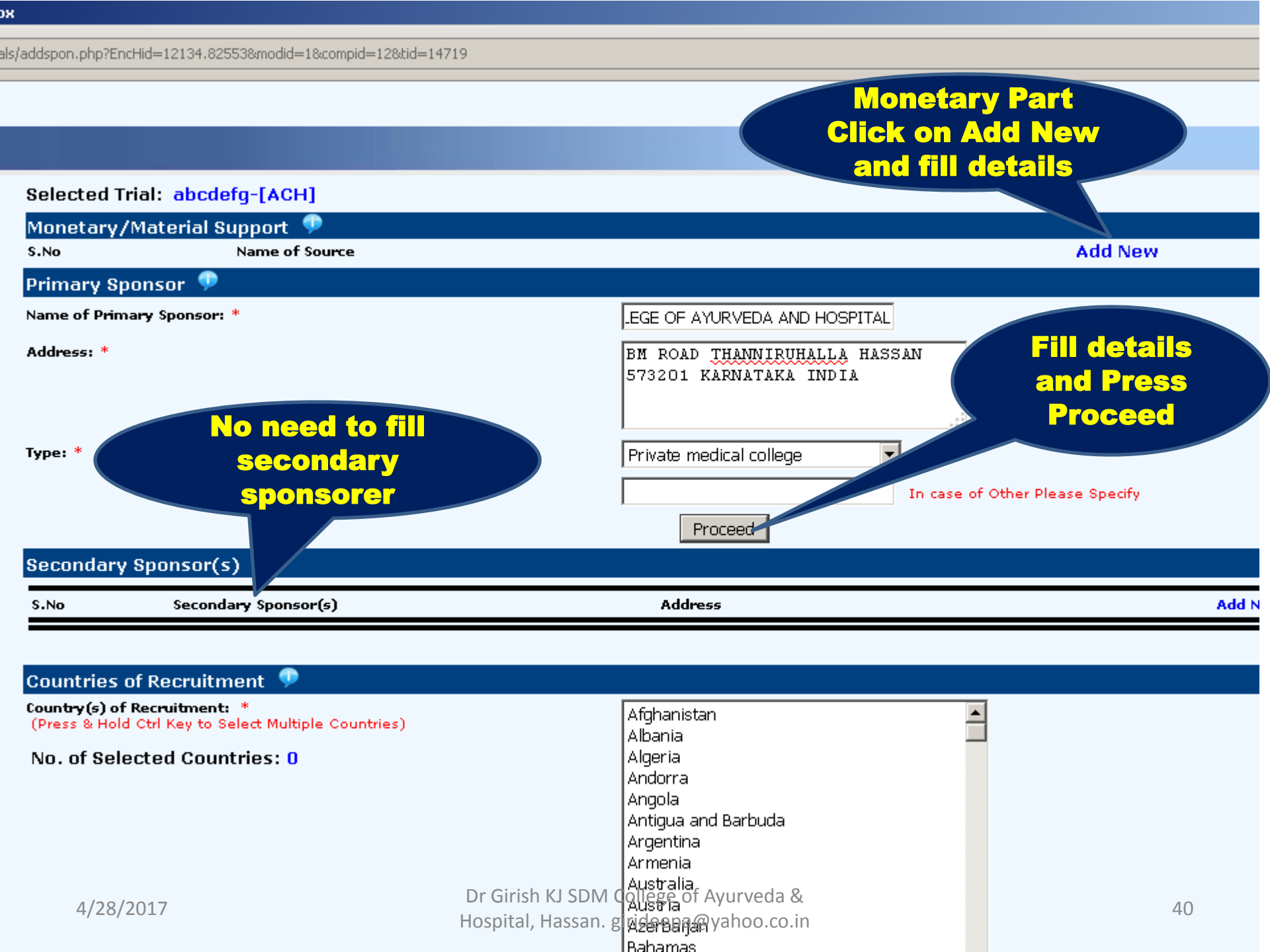
Read the tutorial and fill the Part 3

Primary sponsor	Name and address of the individual, organization, group or other legal person taking responsibility for securing the arrangements to initiate and/or manage a study (including arrangements to ensure that the study design meets appropriate standards and to ensure appropriate conduct and reporting). The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main source of funding. In commercial trials, the primary sponsor is normally the main applicant for regulatory authorization to begin the study. It may or may not be the main source of funding. In investigator initiated trials, the principal investigator is the primary sponsor, though the affiliated institution may be the main source of funding, and acknowledged under "Source/s of Monetary or Material Support".	Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India College Phone: _____ Email: _____

Read the tutorial and fill the Part 3

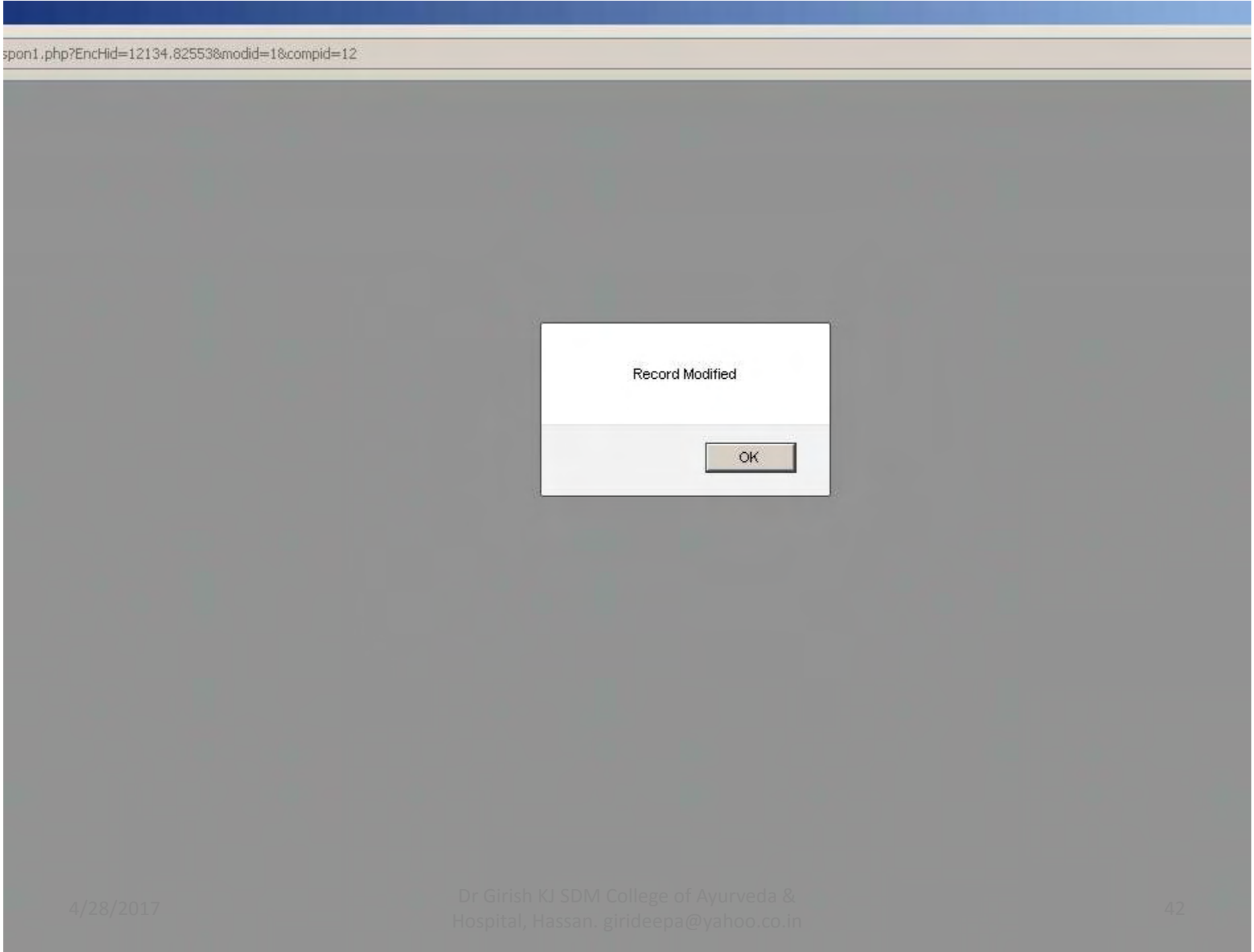
Countries of recruitment	Select from drop down list, countries from which participants are intended to be, or have been recruited. E.g.: India - for trials conducted only in India; India, USA, France - for multi-country trials (as the case may be)	India



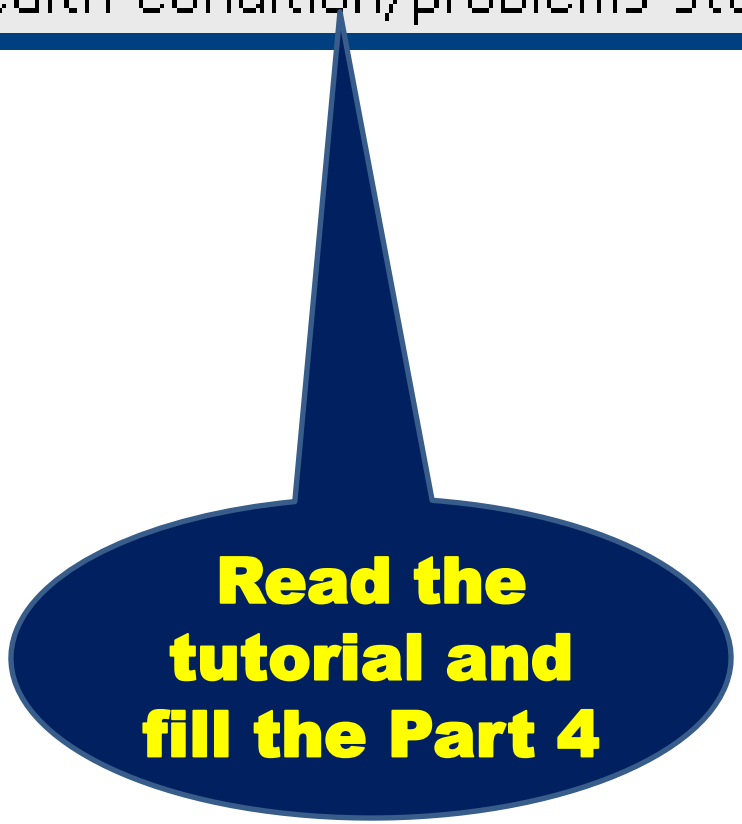


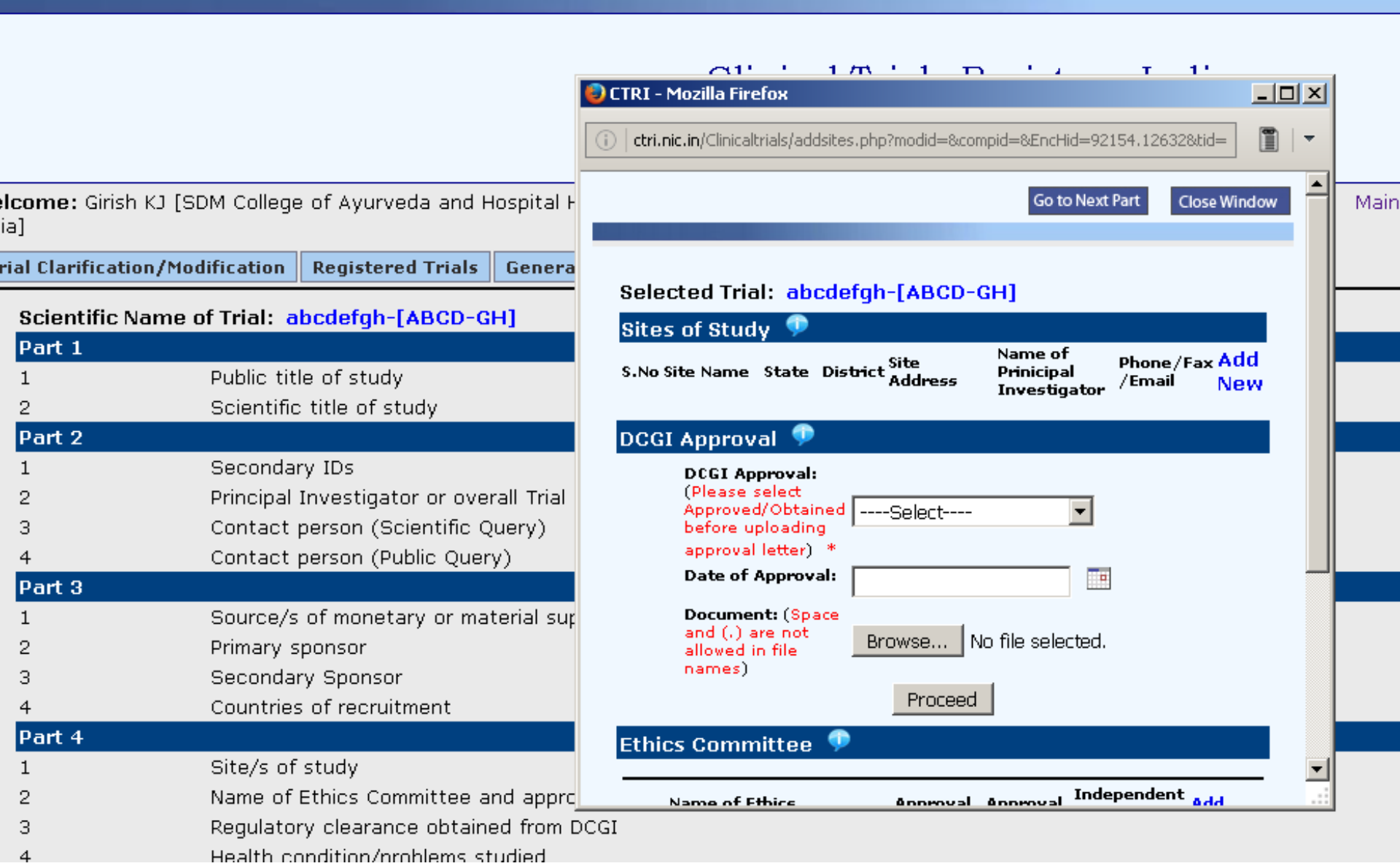
Dr Girish KJ SDM College of Ayurveda & Hospital, Hassan. girideepa@yahoo.co.in


Proceed
Secondary Sponsor(s)
S.No
Secondary Sponsor(s)
Address
Countries of Recruitment
Country(s) of Recruitment: *
(Press & Hold Ctrl Key to Select Multiple Countries)
No. of Selected Countries: 0
Haiti
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran (Islamic Republic of)
Iraq
Ireland
Israel
Italy
Jamaica
Japan
Jordan
Proceed
Click on India and press Proceed


spon1.php?EncHid=12134.82553&modid=1&compid=12
Record Modified
OK

Part 4	
1	Site/s of study
2	Name of Ethics Committee and approval status
3	Regulatory clearance obtained from DCGI
4	Health condition/problems studied




lcome: Girish KJ [SDM College of Ayurveda and Hospital H
ia]
rial Clarification/Modification
Registered Trials
Genera
Scientific Name of Trial: abcdefgh-[ABCD-GH]
Part 1
1 Public title of study
2 Scientific title of study
Part 2
1 Secondary IDs
2 Principal Investigator or overall Trial
3 Contact person (Scientific Query)
4 Contact person (Public Query)
Part 3
1 Source/s of monetary or material sup
2 Primary sponsor
3 Secondary Sponsor
4 Countries of recruitment
Part 4
1 Site/s of study
2 Name of Ethics Committee and apprc
3 Regulatory clearance obtained from DCGI
4 Health condition/problems studied
CTRI - Mozilla Firefox
ctri.nic.in/Clinicaltrials/addsites.php?modid=&compid=&EncHid=92154.12632&tid=
Go to Next Part
Close Window
Main
Selected Trial: abcdefgh-[ABCD-GH]
Sites of Study
S.No Site Name State District Site Address Name of Prinicipal Investigator Phone/Fax /Email Add New
DCGI Approval
DCGI Approval: (Please select Approved/Obtained before uploading approval letter) *
----Select----
Date of Approval:
Document: (Space and (.) are not allowed in file names)
Browse...
No file selected.
Proceed
Ethics Committee
Name of Ethics
Approval
Approval
Independent
Add

Site/s of study	List all site/s within India including the site address as well as the complete address, email, telephone number and Fax No of responsible contact person at each site (This individual should be a medically qualified person and to whom the EC approval is addressed, i.e. the PI; in case a separate person is mentioned, the PI should also be mentioned in any of the other contact person details ("PI or Overall trial coordinator, Contact Person (Scientific query or Public query).	Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India College Phone: _____ Email: _____

Read the tutorial and fill the Part 4

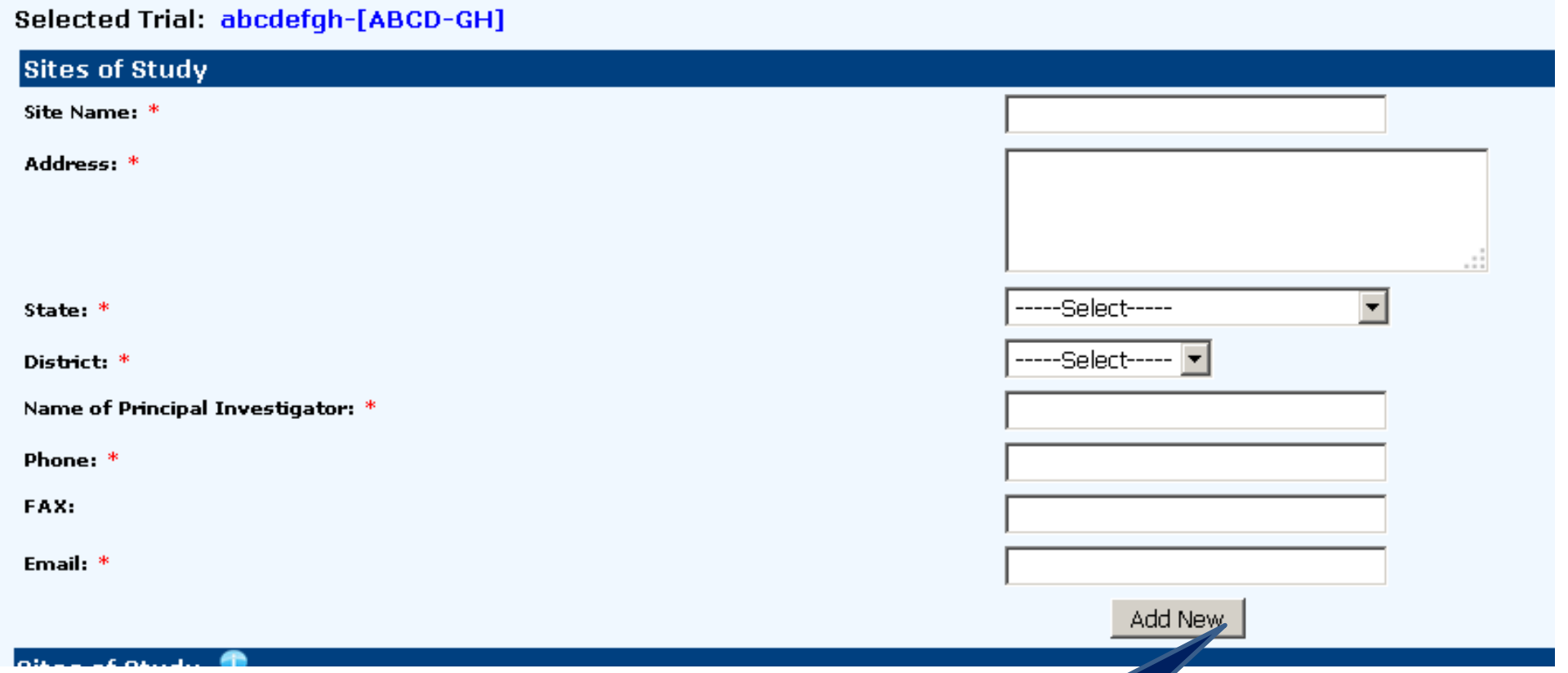
Selected Trial: abcdefgh-[ABCD-GH]

Sites of Study

S.No	Site Name	State	District	Site Address	Name of Prinicipal Investigator	Phone/Fax/Email	Add New

DCGI Approval

Click on Add New and fill the details



Fill the details and click on Ad New Button

Selected Trial: abcdefg-[ACH]

Modify Site

Site Name: *	SRI DHARMASTHALA MANJUNATHE
Address: *	BM ROAD THANNIRUHALLA HASSAN 573201
State: *	KARNATAKA
District: *	Hassan
Name of Principal Investigator: *	DR XYZ
Phone: *	1234567890
FAX:	
Email: *	abcd@abcd.com

Modify

Sites of Study

S.No	Site Name	State	District	Site Address	Name of P
1	SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL HASSAN	KARNATAKA	Hassan	BM ROAD THANNIRUHALLA HASSAN 573201	DR XYZ

After filling this is how it looks

Regulatory clearance obtained from DCGI	Mention whether approval has been taken from Drugs Controller General (India) [DCGI] or not. If DCGI has been notified, the same should be selected. **It is the responsibility of the Sponsor to ascertain whether or not DCGI approval is required for a particular trial**	No

Read the tutorial and fill the Part 4

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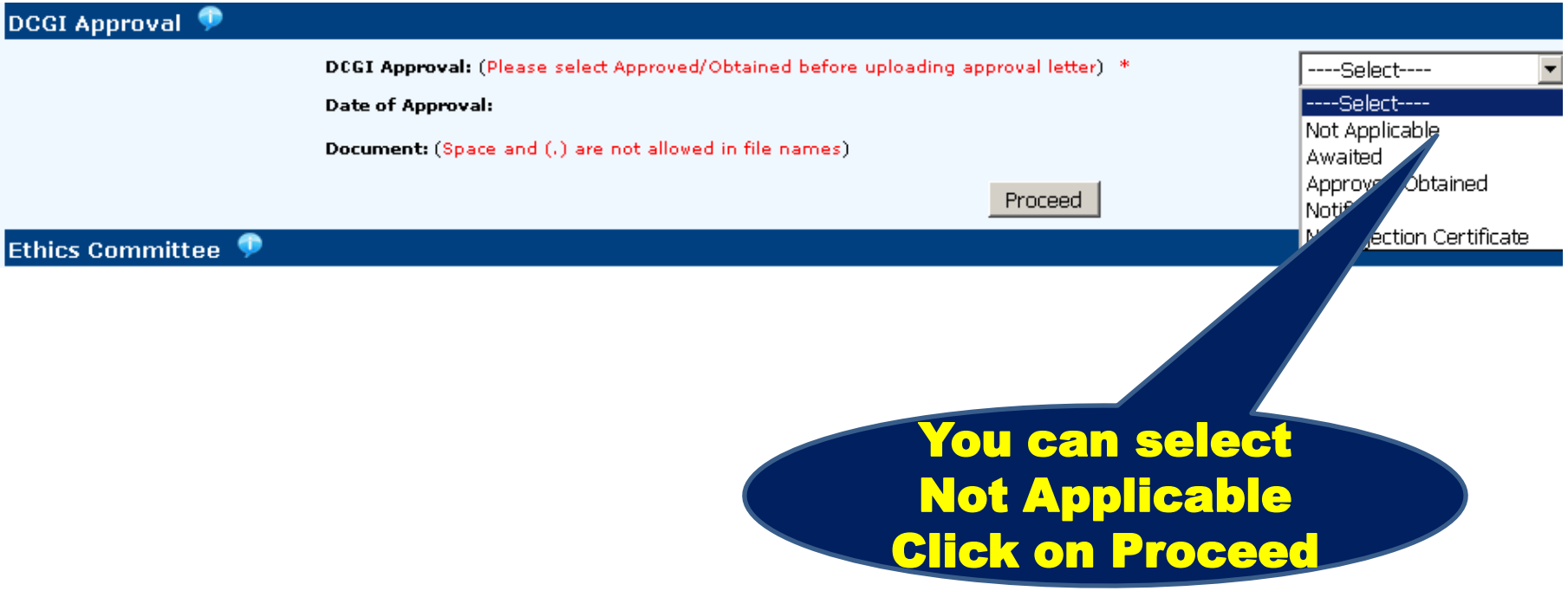

DCGI Approval
DCGI Approval: (Please select Approved/Obtained before uploading approval letter) *
Date of Approval:
Document: (Space and (.) are not allowed in file names)
Proceed
Ethics Committee
----Select----
----Select----
Not Applicable
Awaited
Obtained
ection Certificate
You can select
Not Applicable
Click on Proceed

Sites of Study

S.No	Site Name	State	District	Site Address	Name of Prinicipal Investigator
1	SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL HASSAN	KARNATAKA	Hassan	BM ROAD THANNIRUHALLA HASSAN 573201	DR XYZ

DCGI Approval

DCGI Approval: (Please select Approved/Obtained before uploading approval letter) *

Not Applicable

Date of Approval:

Document: (Space and (.) are not allowed in file names)

Browse... No file selected.

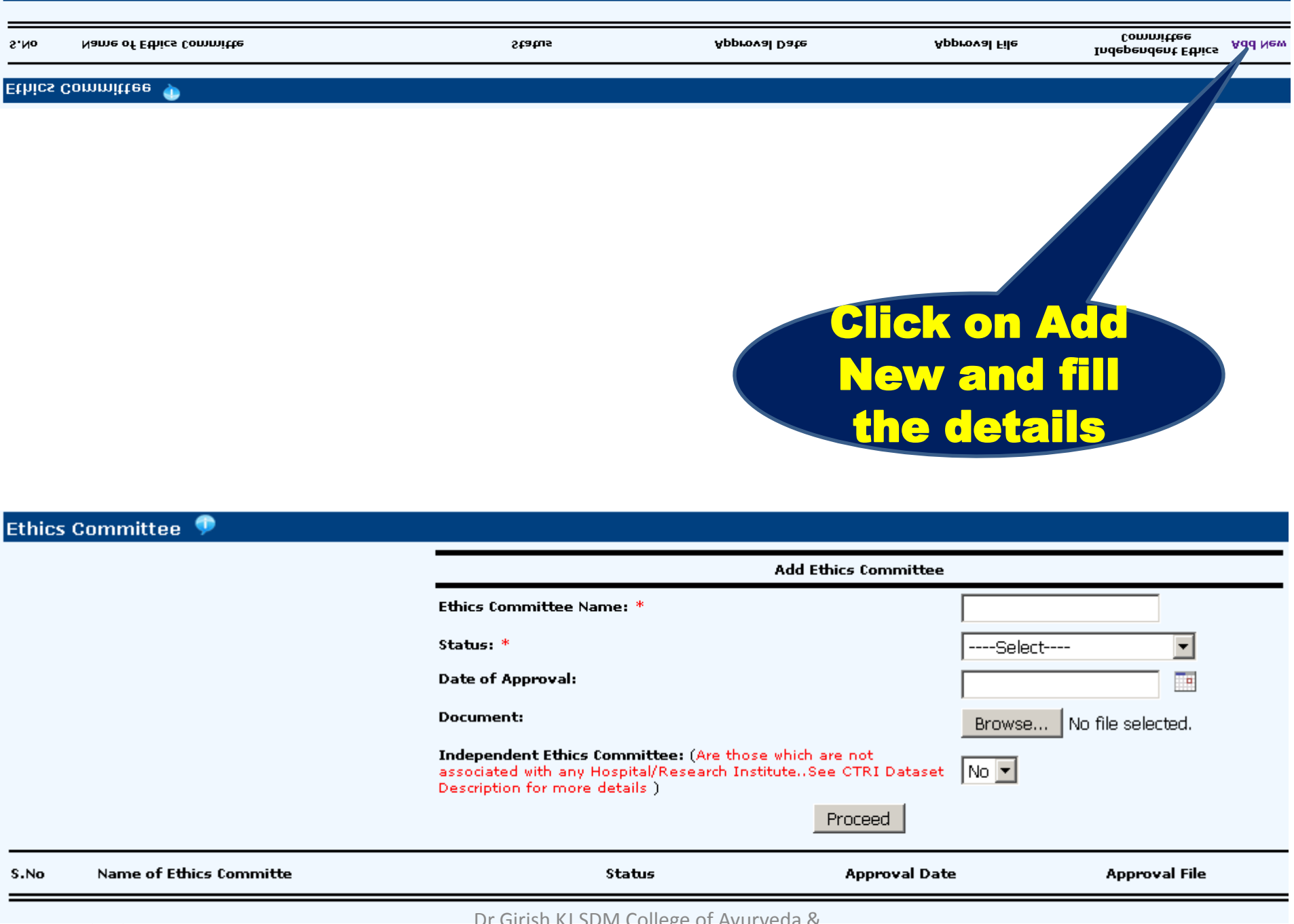
Proceed

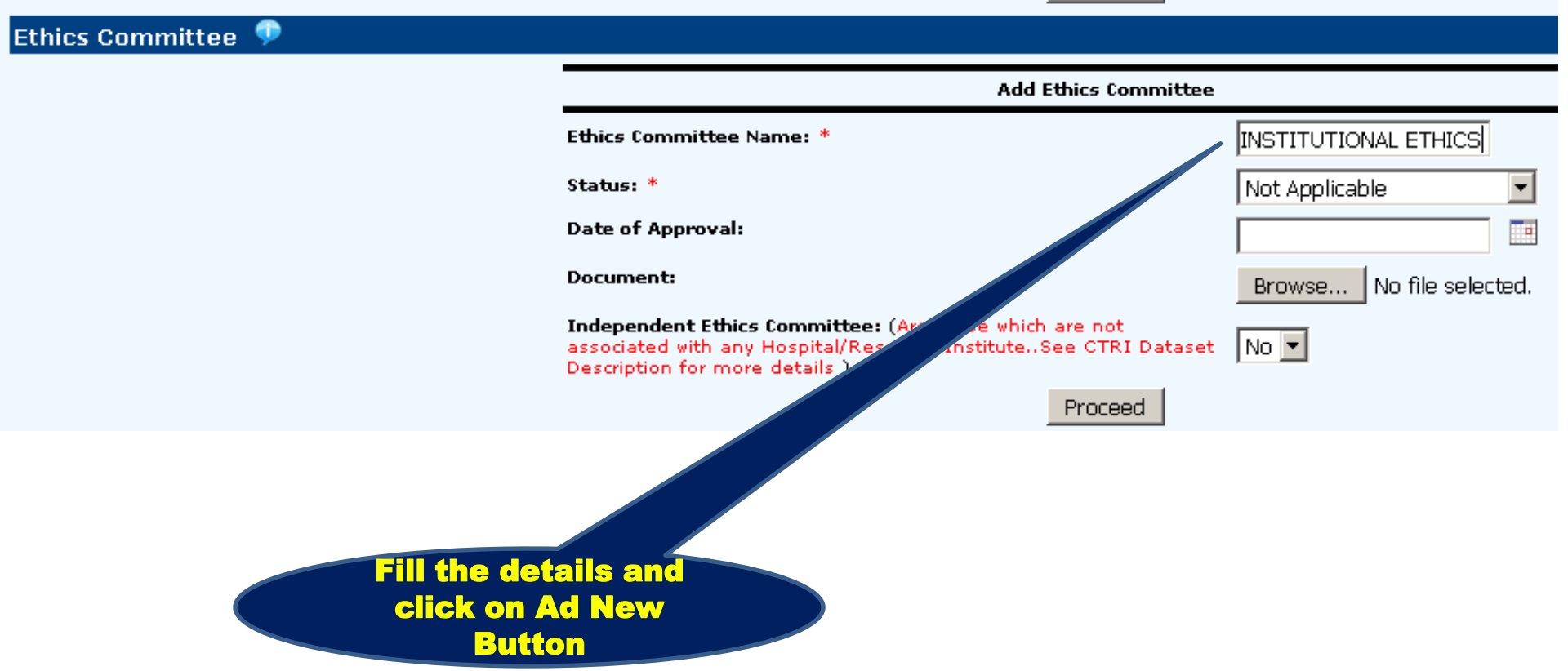
After filling this is how it looks

Name of Ethics Committee and approval status	Provide name of Ethics Committee (EC) from whom approval has been sought; for multi-centre trials, add names of all ECs from whom approval has been sought; also provide approval status, i.e. submitted for approval or approved with date. Please indicate wh[illegible]er an EC is an Indepe[illegible]nt Ethics Committee o[illegible]t. Menti[illegible] approval status of [illegible]te separately even	Institutional Ethics Committee Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital BM Road Thanniruhalla Hassan 573201 Karnataka India College Phone: _____ Email: _____

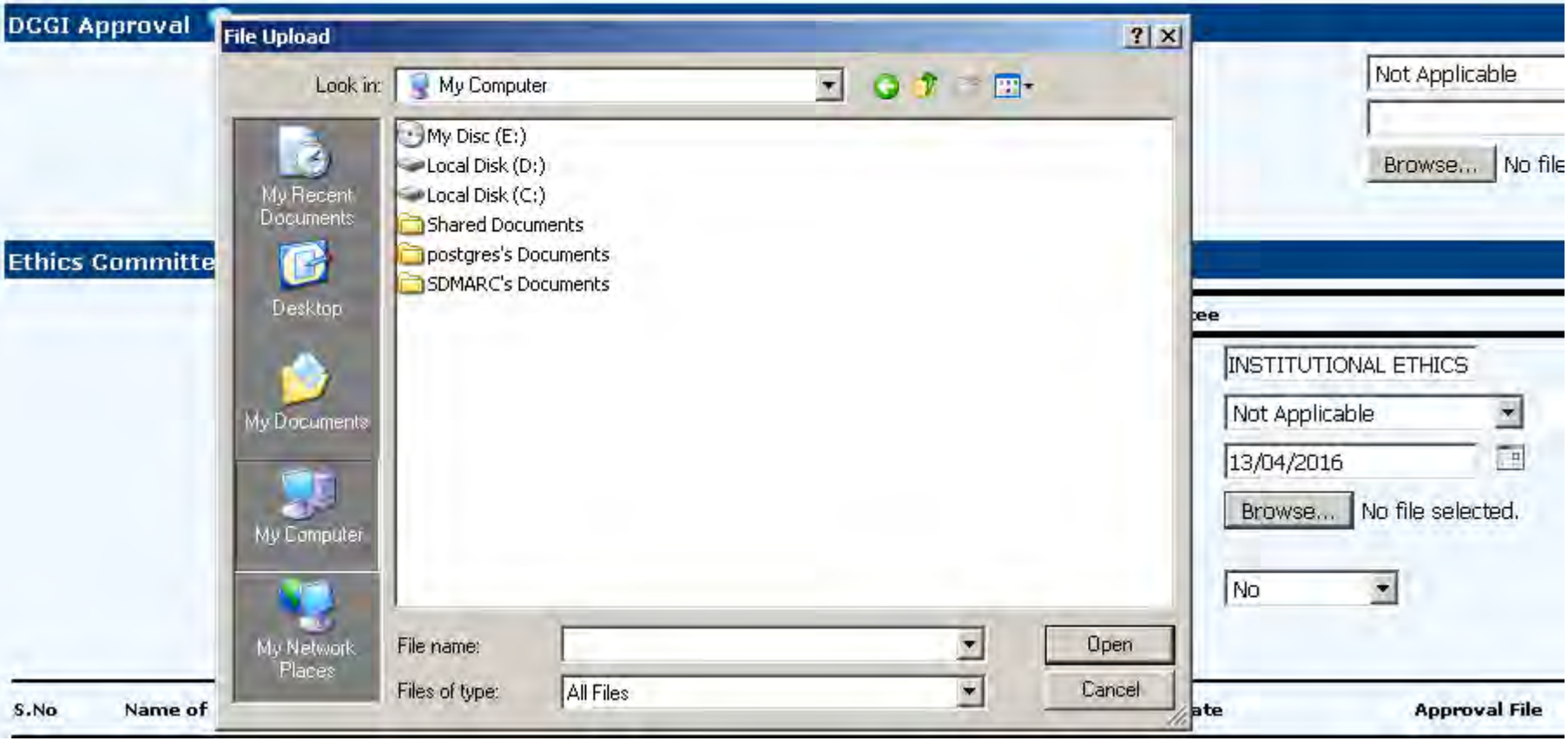
Read the tutorial and fill the Part 4

You have to keep scanned / digital (may be pdf or jgp) copy of your ethics clearance certificate


Click on Add New and fill the details
Ethics Committee
Add Ethics Committee
Ethics Committee Name: *
Status: *
----Select----
Date of Approval:
Document:
Browse...
No file selected.
Independent Ethics Committee: (Are those which are not associated with any Hospital/Research Institute..See CTRI Dataset Description for more details)
No
Proceed
S.No
Name of Ethics Committe
Status
Approval Date
Approval File


Ethics Committee
Add Ethics Committee
Ethics Committee Name: *
INSTITUTIONAL ETHICS
Status: *
Not Applicable
Date of Approval:
Document:
Browse...
No file selected.
Independent Ethics Committee: (Are those which are not associated with any Hospital/Research Institute..See CTRI Dataset Description for more details)
No
Proceed
Fill the details and click on Ad New Button


Ethics Committee
Add Ethics Committee
Ethics Committee Name: *
Status: *
----Select----
----Select----
Submittted/Under Review
Approved
Not Applicable
No Objection Certificate
Independent Ethics Committee: (Are those which are not associated with any Hospital/Research Institute..See CTRI Dataset Description for more details)
Proceed
Make Status as Approved
Fill in the date of approval from IEC certificate and Upload the PDF or JPG file of IEC certificate
S.No
Name of Ethics Committe
Status
Approval Date
Approval File


DCGI Approval
File Upload
Look in:
My Computer
My Disc (E:)
Local Disk (D:)
Local Disk (C:)
Shared Documents
postgres's Documents
SDMARC's Documents
My Recent Documents
Desktop
My Documents
My Computer
My Network Places
File name:
Files of type:
All Files
Open
Cancel
Not Applicable
Browse...
No file
Ethics Committe
INSTITUTIONAL ETHICS
Not Applicable
13/04/2016
Browse...
No file selected.
No
S.No
Name of
Approval File

Ethics Committee

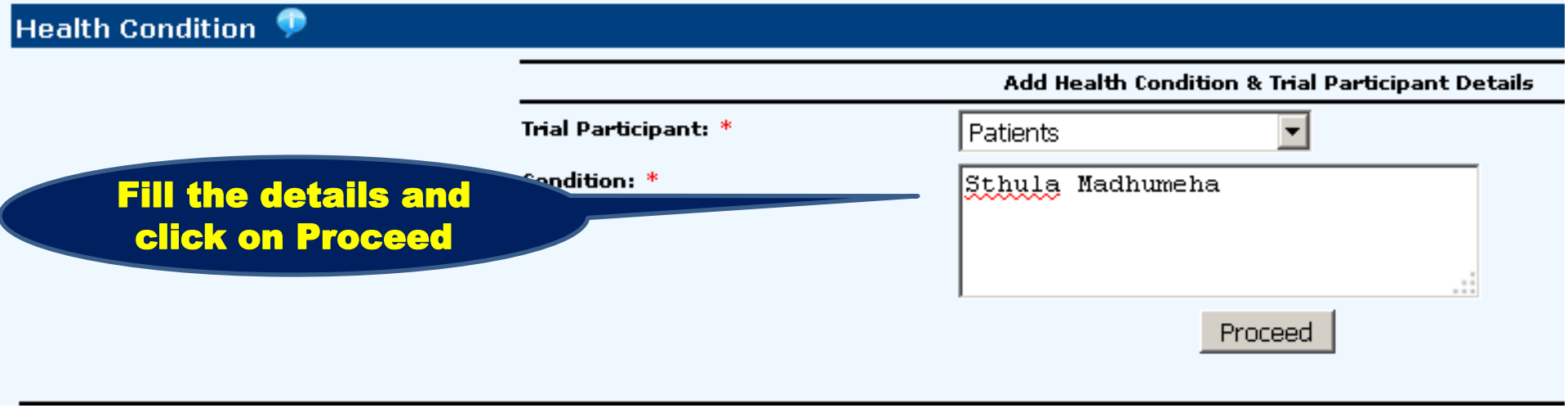
S.No	Name of Ethics Committe	Status	Approval Date	Approval File	Independent Ethics Committee
1	INSTITUTIONAL ETHICS COMMITTEE SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA AND HOSPITAL HASSAN	Not Applicable	--	--	No

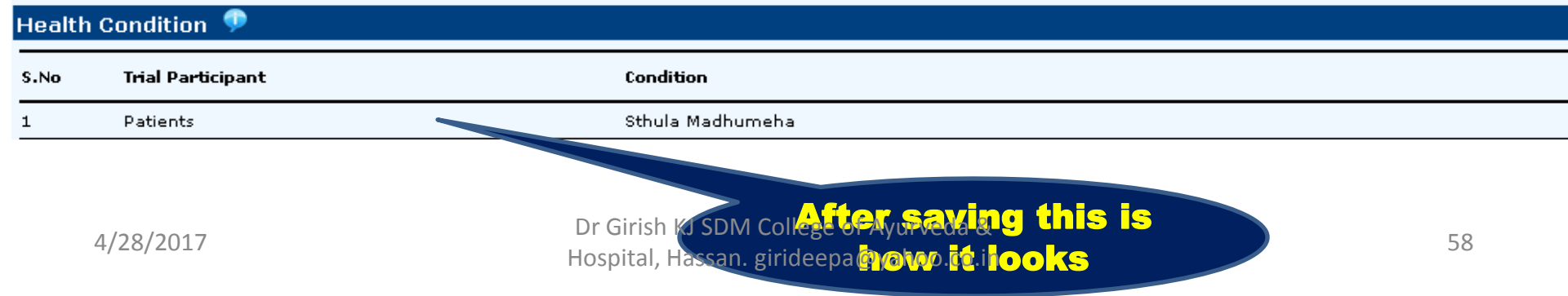
After filling this is how it looks But Status should be approved and file should be uploaded

Dr Girish KJ SDM College of Ayurveda & Hospital, Hassan. girideepa@yahoo.co.in

Health condition/problem studied	State the primary health condition(s) or problem(s) studied. If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g., preventative or screening interventions), enter the particular health condition(s) or problem(s) being prevented or screened **Example:** Type 2 Diabetes Mellitus; Hypertension	


Health Condition
S.No
Trial Participant
Condition
Add Health Condition & Trial Participant Details
Click on Add Health Condition & Trial Participant Details


Health Condition
Add Health Condition & Trial Participant Details
Trial Participant: *
Patients
Condition: *
Sthula Madhumeha
Proceed
Fill the details and click on Proceed


Health Condition
S.No
Trial Participant
Condition
1
Patients
Sthula Madhumeha
After saving this is how it looks

Part 5

1 Study Type

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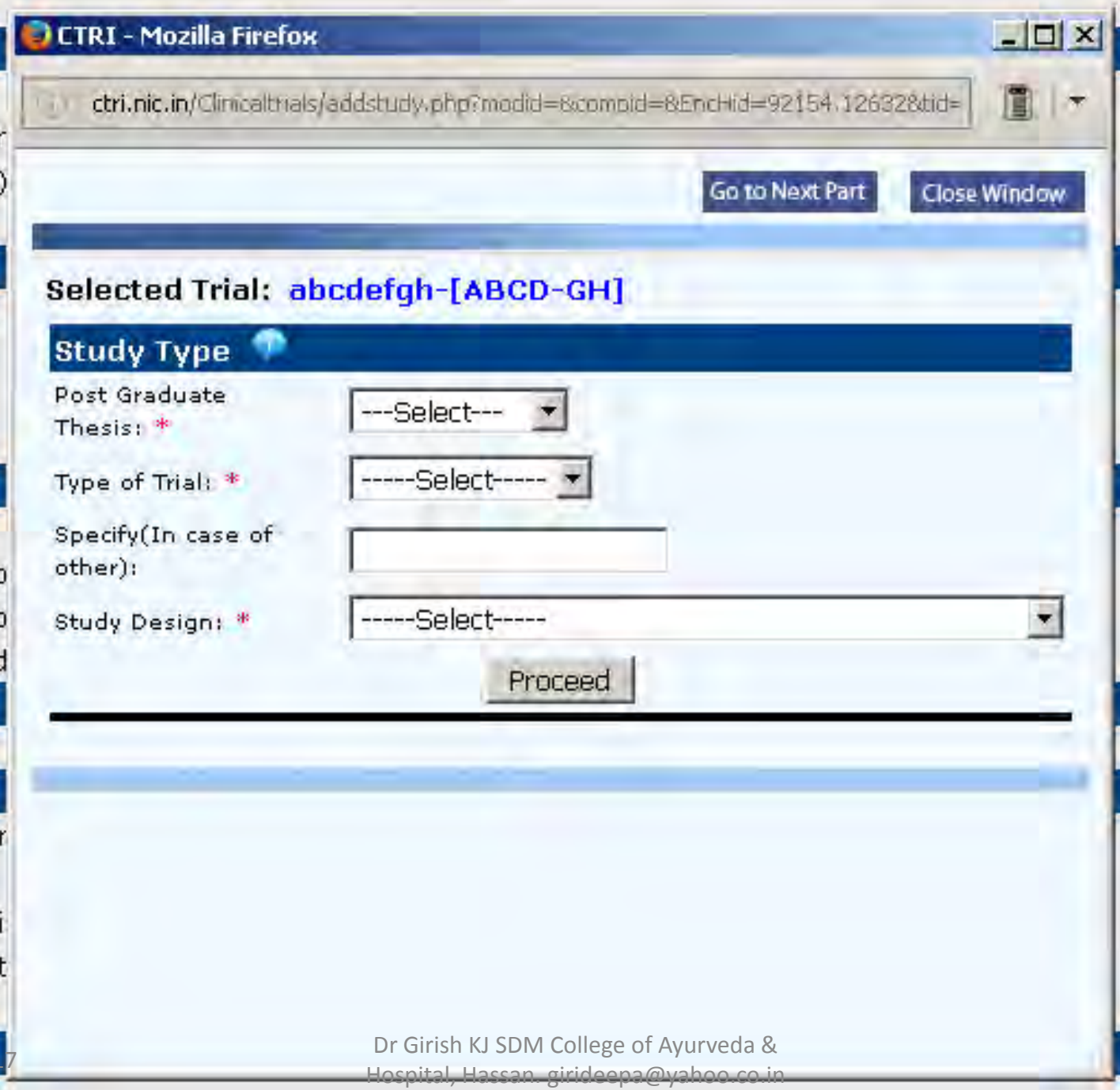
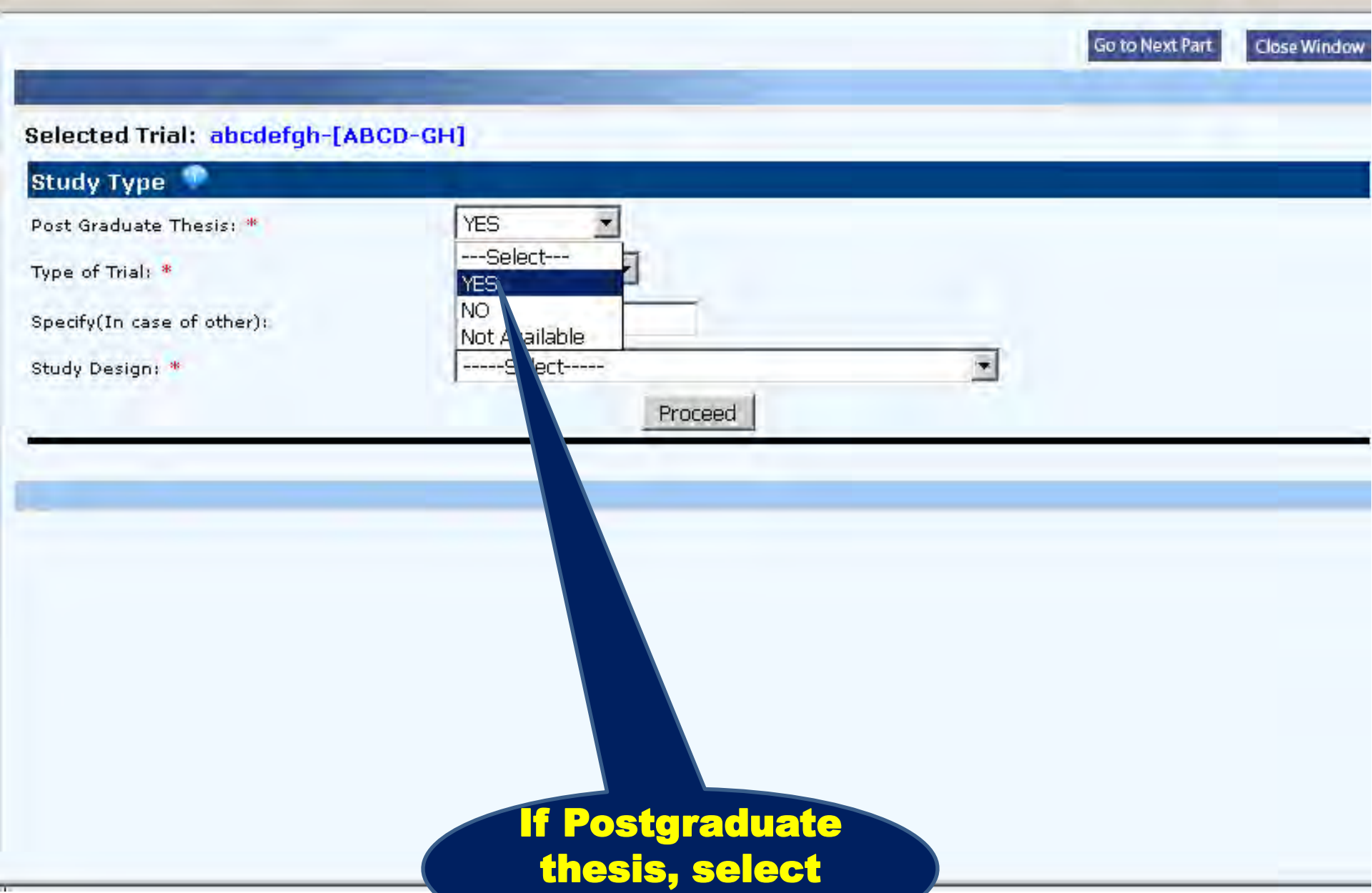

CTRI - Mozilla Firefox
ctri.nic.in/Clinicaltrials/addstudy.php?modid=&comoid=&EncHid=92154.12632&tid=
Go to Next Part
Close Window
Selected Trial: abcdefgh-[ABCD-GH]
Study Type
Post Graduate Thesis: *
---Select---
Type of Trial: *
-----Select-----
Specify(In case of other):
Study Design: *
-----Select-----
Proceed

Study type	Please indicate if trial part of post-graduation thesis Please select whether the trial is an Interventional trial, Observational trial or Post marketing surveillance **Interventional Trial:** An interventional trial is one that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on	This study is part of Post-graduation thesis Interventional study clinical trial

Read the tutorial carefully



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Study type	Please indicate if trial part of post-graduation thesis Please select whether the trial is an Interventional trial, Observational trial or Post marketing surveillance **Interventional Trial:** An interventional trial is one that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on outcomes. Choose the intervention that is best suited for the trial, more than one option may be selected according to the intervention/s being used; e.g. Drug & Ayurveda	This study is part of Post-graduation thesis Interventional study clinical trial

Observational Trial

An observational trial is one where no experimental intervention or treatment is given to human participants. In this type of trial, the investigator only observes the effect of a risk factor, diagnostic test, or treatment on a particular outcome.

Choose the intervention that is best suited for the trial.

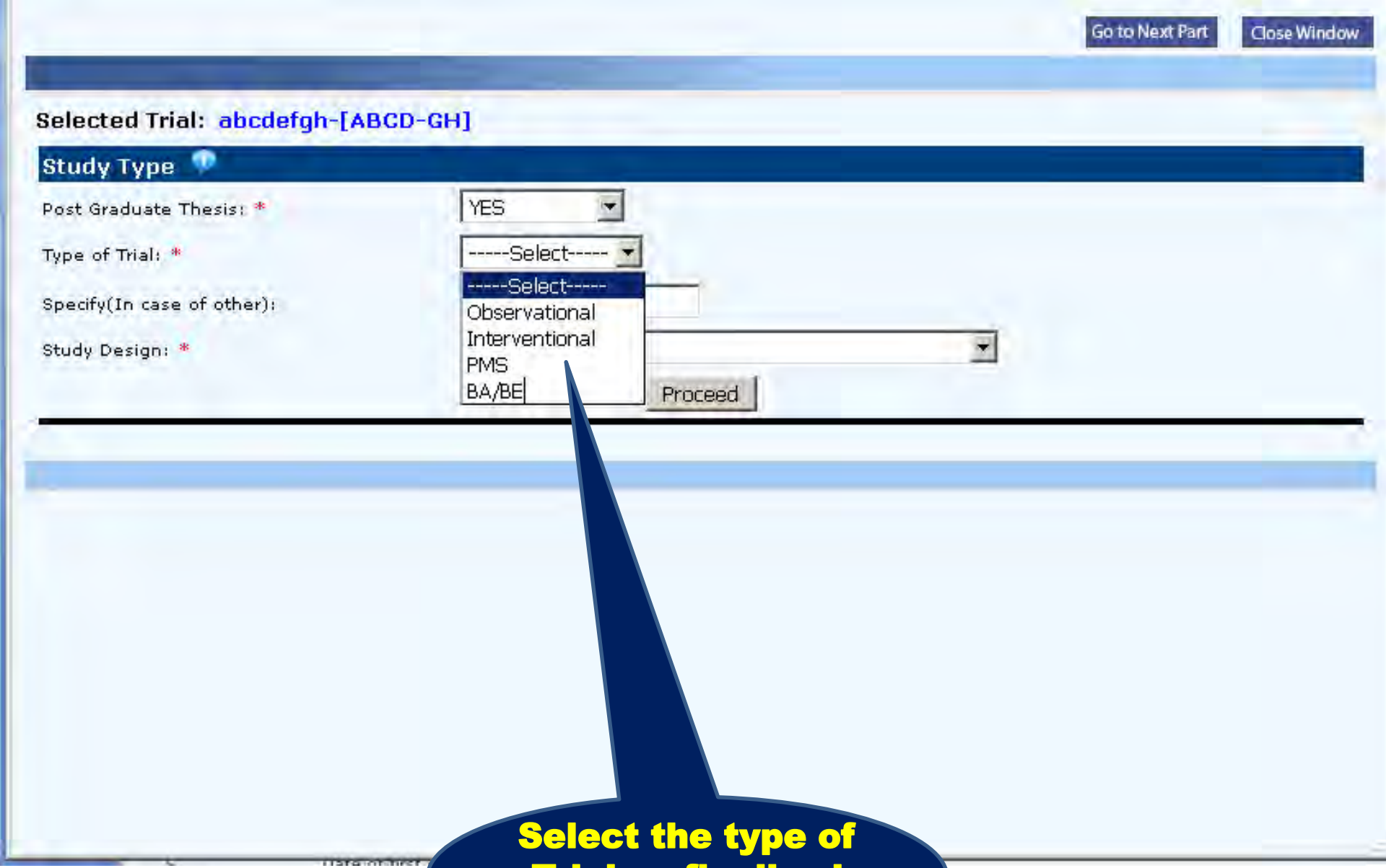
PMS: Post marketing surveillance study

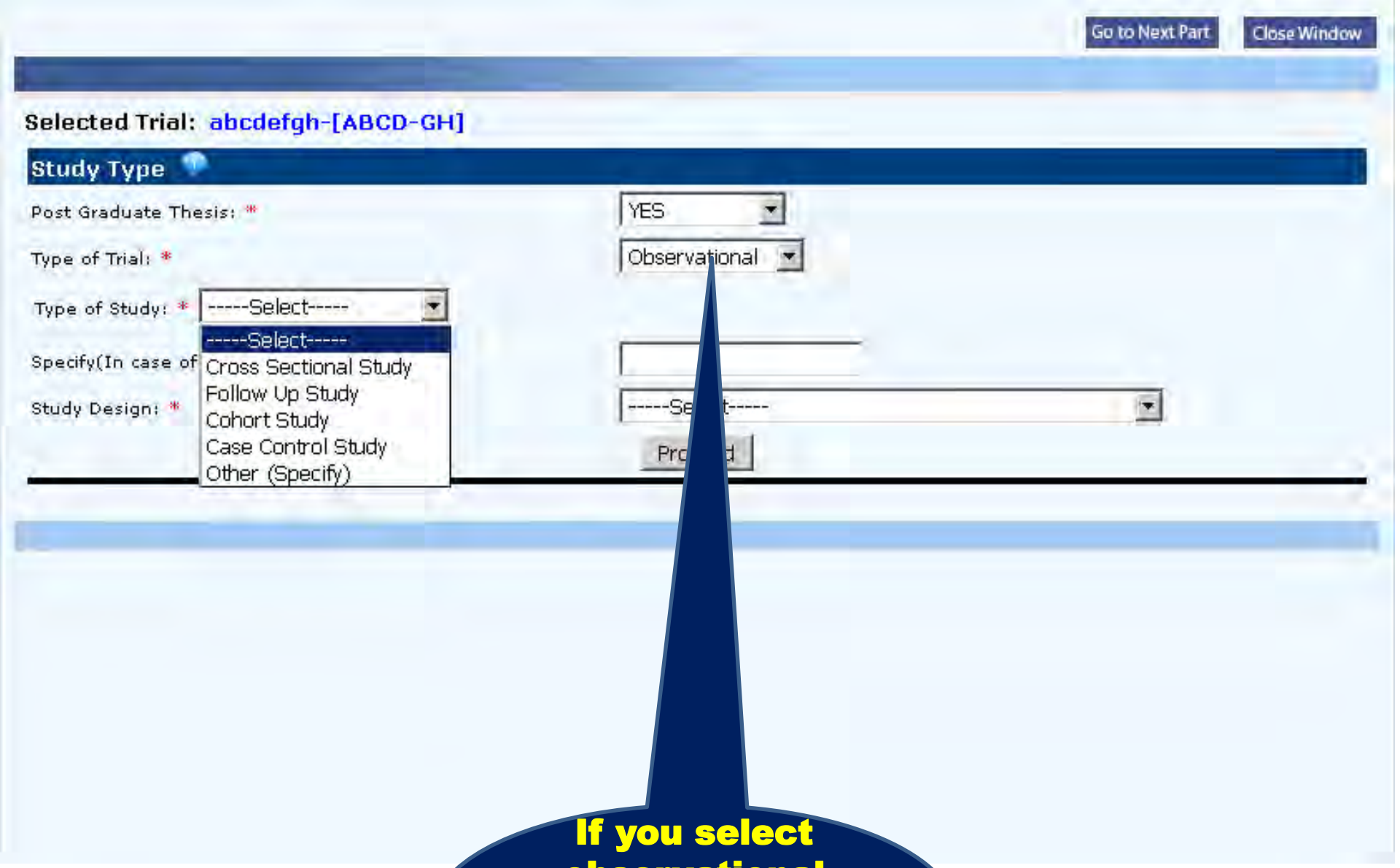
Choose a Study Design from the list provided

Examples:

Single arm trial
Non-randomized, placebo controlled trial
Non-randomized, active controlled trial
Non-randomized, multiple arm trial
Randomized parallel group trial
Randomized, parallel group, placebo controlled trial
Randomized, parallel group, active controlled trial
Randomized, parallel group, multiple arm trial
Randomized, crossover trial
Cluster randomized trial
Randomized factorial trial

Read the tutorial carefully


Go to Next Part
Close Window
Selected Trial: abcdefgh-[ABCD-GH]
Study Type
Post Graduate Thesis: *
YES
Type of Trial: *
-----Select-----
Specify(In case of other):
Study Design: *
-----Select-----
Observational
Interventional
PMS
BA/BE
Proceed
Select the type of Trial as finalized in your protocol



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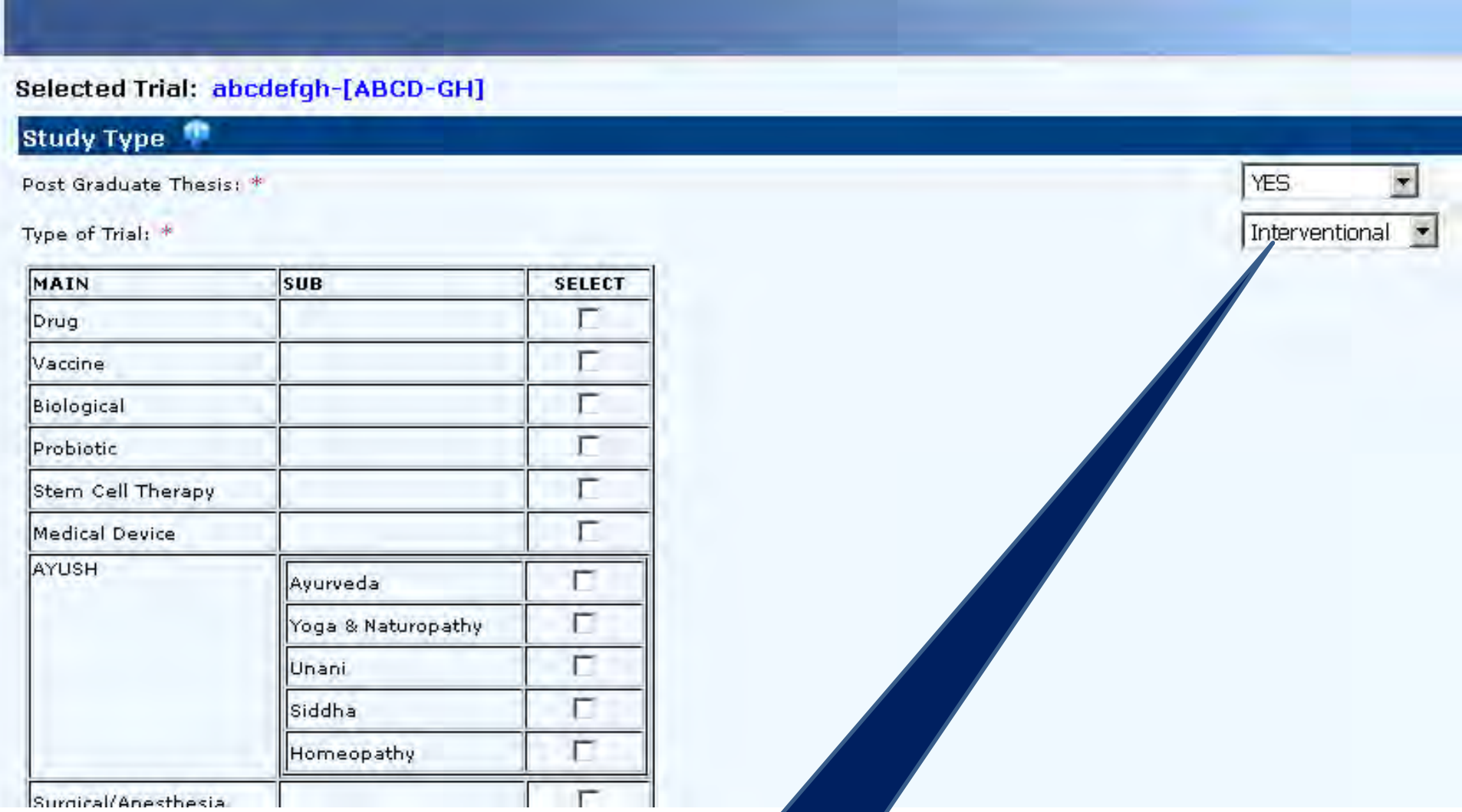

If your study is interventional, you have select Ayurveda

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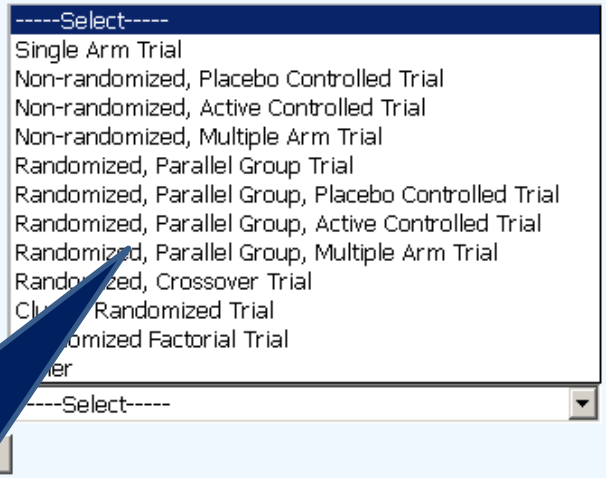
Stem Cell Therapy		☐
Medical Device		☐
AYUSH	Ayurveda	☑
	Yoga & Naturopathy	☐
	Unani	☐
	Siddha	☐
	Homeopathy	☐
Surgical/Anesthesia		☐
Radiation Therapy		☐
Diagnostic		☐
Preventive		☐
Screening		☐
Dentistry		☐
Physiotherapy (Not Including YOGA)		☐
Process of Care Changes		☐
Behavioral		☐
Nutraceutical		☐
Other (Specify)		☐

Specify(In case of other):

Study Design: *



Choose the appropriate study design and click on Proceed (in both observational and interventional also)

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Part 6	
1	Intervention and comparator agent
2	Inclusion & Exclusion Criteria
3	Method of generating randomization sequence
4	Method of allocation concealment
5	Blinding/masking

Part 6

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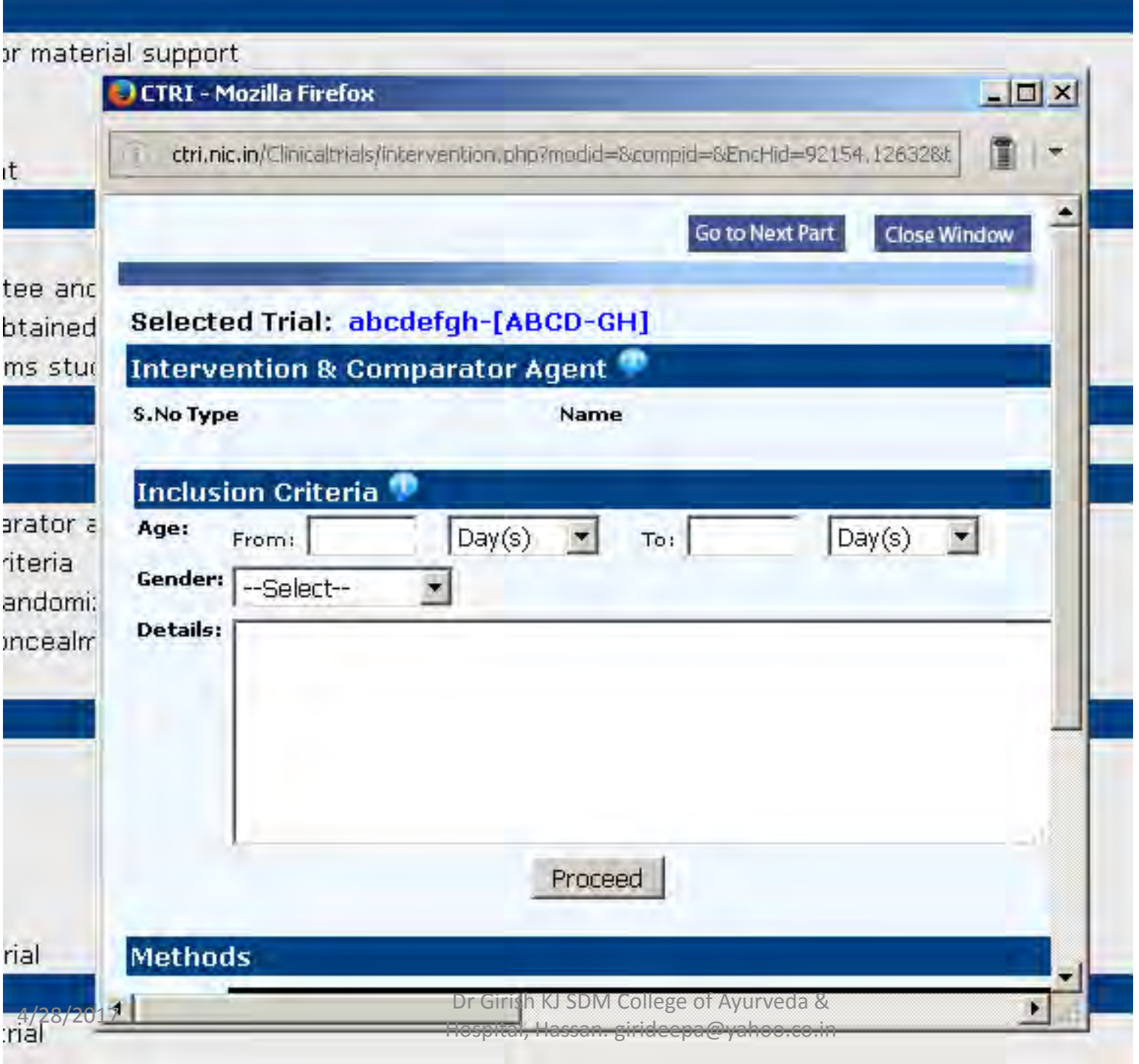
or material support
CTRI - Mozilla Firefox
ctri.nic.in/Clinicaltrials/intervention.php?modid=&compid=&EncHid=92154.12632&t
Go to Next Part
Close Window
Selected Trial: abcdefgh-[ABCD-GH]
Intervention & Comparator Agent
S.No Type
Name
Inclusion Criteria
Age:
From:
Day(s)
To:
Day(s)
Gender:
--Select--
Details:
Proceed
Methods

Intervention and comparator agent	Enter the specific name of the intervention/s and the comparator/control/s being studied. Use the International Non-Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable. If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g., "low-fat diet, exercise"). The control intervention/s is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name/s of that intervention, or enter "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc). **Example:** Ramipril 2.5 mg OD for 12 months Candesartan 16 mg OD for 12 months For observational trials, NIL may be mentioned with trial details mentioned in the Brief Summary.

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elected Trial: abcdefgh-[ABCD-GH]

tervention & Comparator Agent

No Type | Name | Details | Add New

Click on Add New and fill the details

Intervention & Comparator Agent

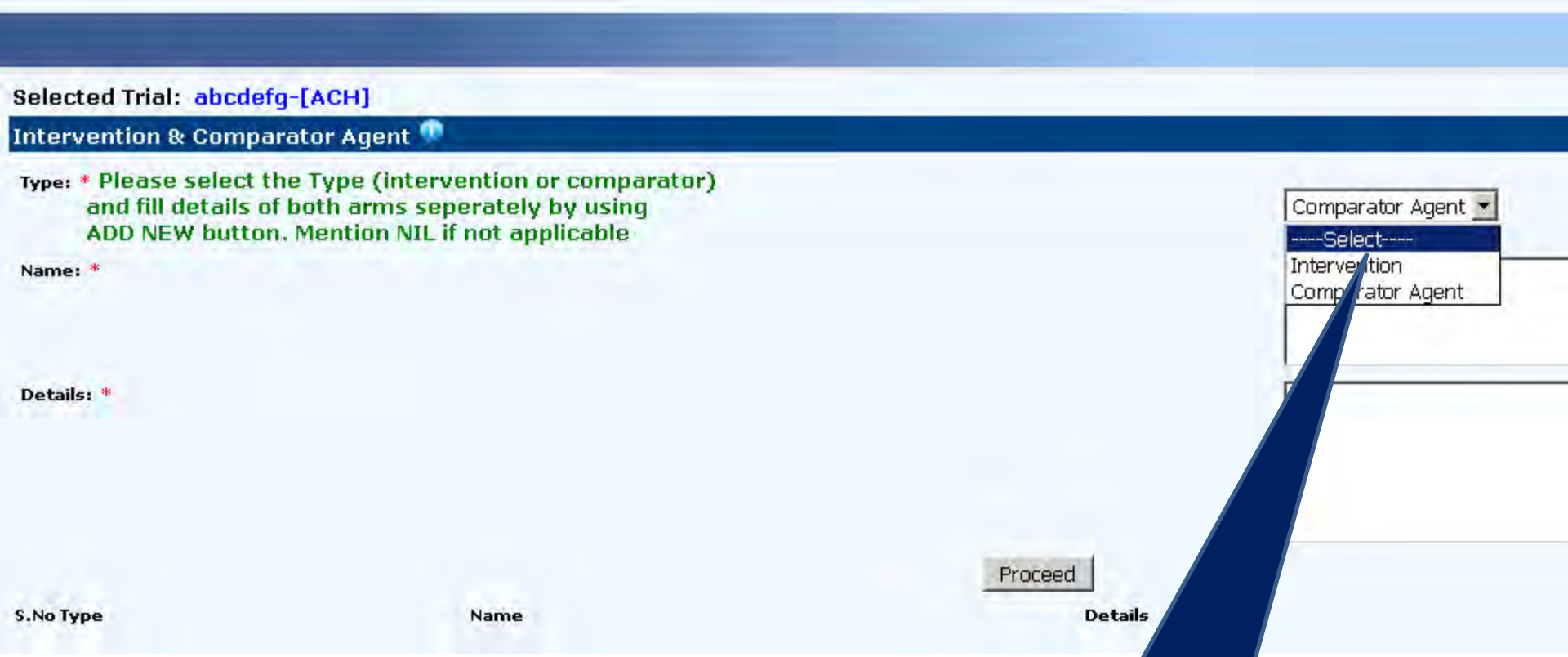
Type: * Please select the Type (intervention or comparator) and fill details of both arms seperately by using ADD NEW button. Mention NIL if not applicable

----Select----

Name: *

Details: *

Proceed



First select Intervention and fill the details and click on Proceed

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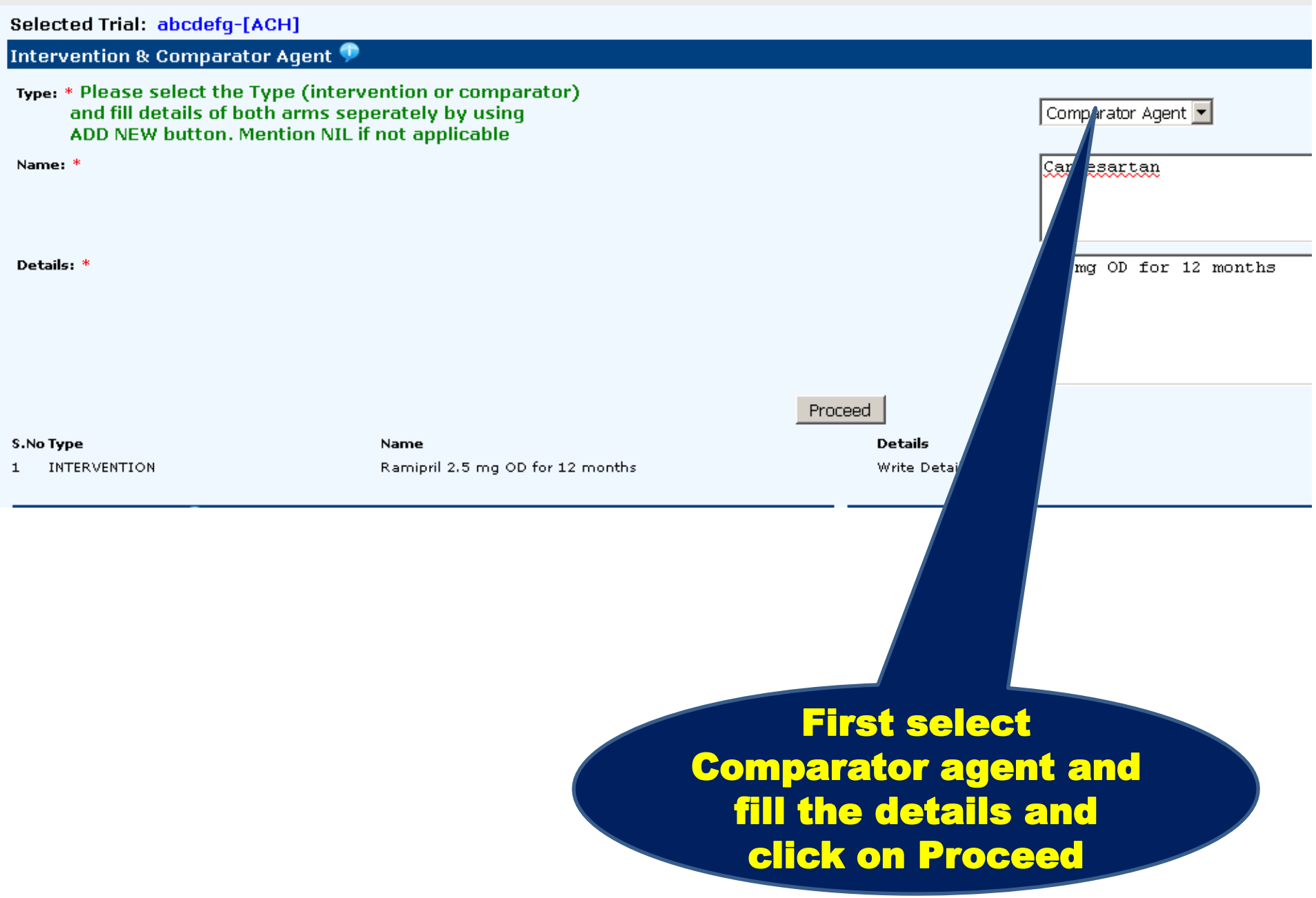
Selected Trial: abcdefg-[ACH]
Intervention & Comparator Agent
Type: * Please select the Type (intervention or comparator) and fill details of both arms seperately by using ADD NEW button. Mention NIL if not applicable
Comparator Agent
Name: *
Details: *
mg OD for 12 months
Proceed
S.No Type
Name
Details
1 INTERVENTION
Ramipril 2.5 mg OD for 12 months
First select Comparator agent and fill the details and click on Proceed

Inclusion/ Exclusion criteria	Inclusion and exclusion criteria for participant selection, including age and sex. Age and sex to be mentioned in specific boxes. **Example:** Inclusion criteria Adult males or females with a diagnosis of type 2 diabetes mellitus and hypertension Hypertension defined as systolic blood pressure of 140 mmHg or diastolic blood pressure of 90 mmHg Diabetes defined as those patients with fasting glucose levels of ≥ 126 mg/dl or random blood glucose > or = 200 mg/dl, HbA1c > or = 6.5%, 2 h blood glucose on 75 g oral glucose tolerance test (OGTT) > or = 200 mg/dl, or current treatment with hypoglycemic therapy). **Exclusion Criteria:** A history of coronary heart disease or stroke, serum creatinine ≥1.5 mg/dl, albuminuria ≥40 µg/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents. **Please separate each criteria by using the "Enter" button**

Read the tutorial carefully

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Selected Trial: abcdefg-[ACH]

Intervention & Comparator Agent

S.No	Type	Name	Details
1	INTERVENTION	Ramipril 2.5 mg OD for 12 months	Write Details
2	COMPARATOR AGENT	Candesartan	16 mg OD for 12 months

Inclusion Criteria

Age: From: 18 Year(s) To: 60 Year(s)

Gender: Male & Female

Details:

Diabetes defined as those patients with fasting glucose levels of > 126 mg/dl or random blood glucose > or = 200 mg/dl, HbA1c > or = 6.5%, 2 h blood glucose on 75 g oral glucose tolerance test (OGTT) > or = 200 mg/dl, or current treatment with hypoglycemic therapy).

Proceed

Exclusion Criteria

Details:

A history of coronary heart disease or stroke, serum creatinine >1.5 mg/dl, albuminuria >40 µg/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents

Proceed

Fill the age details and gender and then details of Inclusion and Proceed

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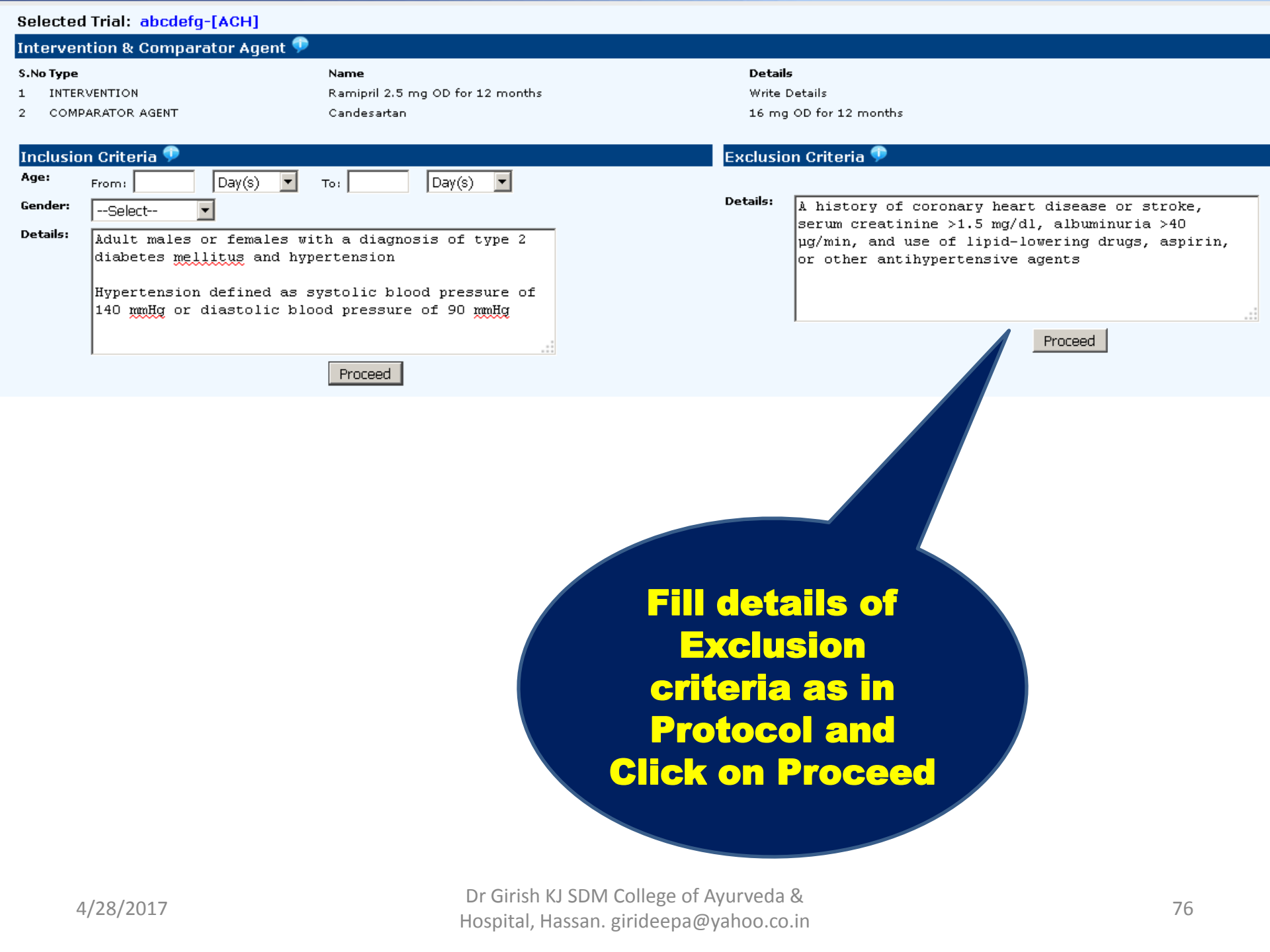
Selected Trial: abcdefg-[ACH]
Intervention & Comparator Agent
S.No Type
Name
Details
1 INTERVENTION
Ramipril 2.5 mg OD for 12 months
Write Details
2 COMPARATOR AGENT
Candesartan
16 mg OD for 12 months
Inclusion Criteria
Age:
From:
Day(s)
To:
Day(s)
Gender:
--Select--
Details:
Adult males or females with a diagnosis of type 2 diabetes mellitus and hypertension
Hypertension defined as systolic blood pressure of 140 mmHg or diastolic blood pressure of 90 mmHg
Proceed
Exclusion Criteria
Details:
A history of coronary heart disease or stroke, serum creatinine >1.5 mg/dl, albuminuria >40 µg/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents
Proceed
Fill details of Exclusion criteria as in Protocol and Click on Proceed

Method of generating randomization sequence	The method used to generate the random allocation sequence. The main purpose of randomization is to eliminate selection bias and balance known or unknown confounding factors in order to create a control group that is as similar as possible to the treatment group. Methods for randomly assigning participants to groups, which limits bias, include the use of a table of random numbers and a computer program that generates random numbers. Methods of assignment that are prone to bias include alternating assignment or assignment by date of birth or hospital admission number. **Example:** Coin toss, lottery, toss of dice, shuffling cards etc Random number table Computer generated randomization Permuted block randomization, fixed Permuted block randomization, variable Stratified randomization Stratified block randomization Adaptive randomization, such as minimization Other, describe

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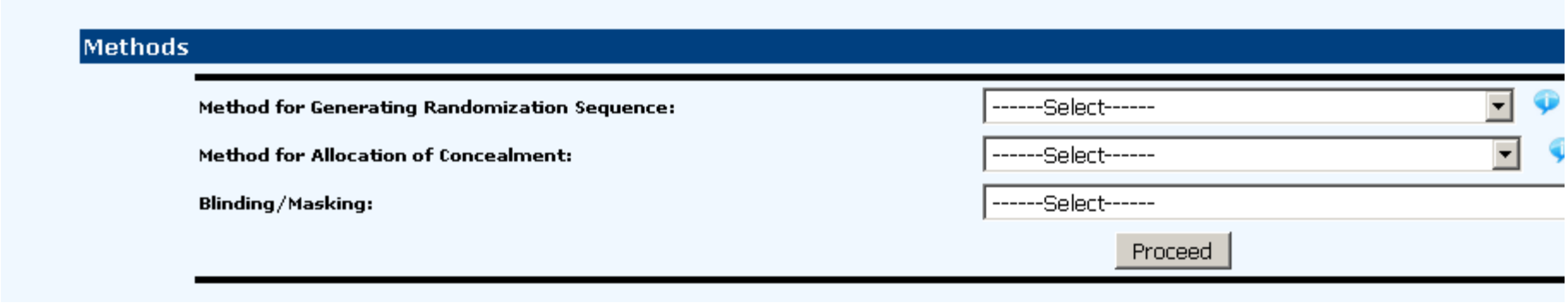
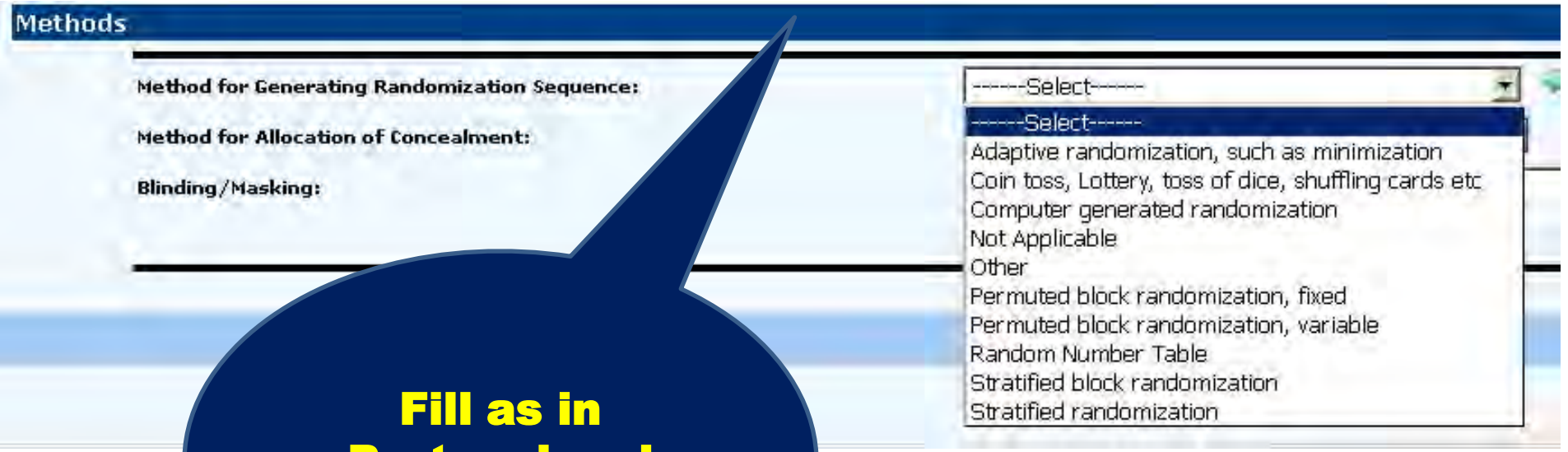
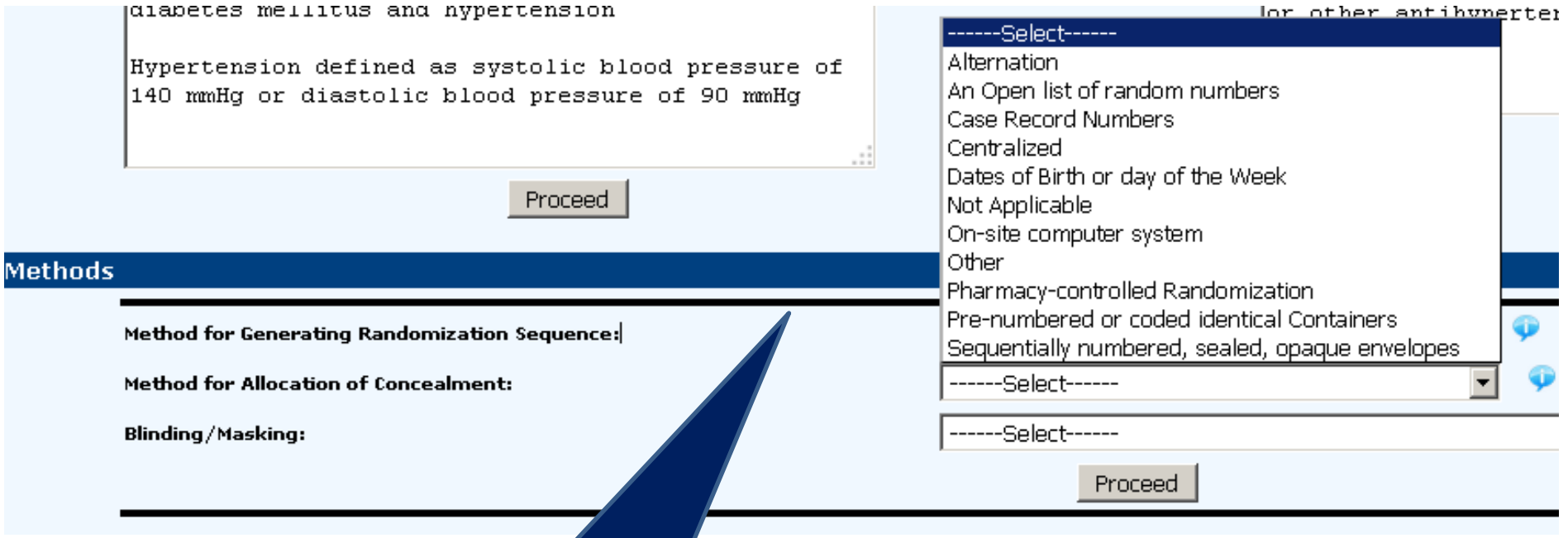




Fill as in Protocol and Click on Proceed

Blinding/masking	Blinding refers to methods used to prevent participants and investigators from knowing what interventions are being used to reduce bias. Open trials do not use blinding. Masking refers to the methods used to camouflage interventions to achieve blinding. Examples: • Open label • Participant blinded • Investigator blinded • Outcome assessor blinded • Double blind double dummy • Participant and Investigator blinded • Participant and outcome assessor blinded • Participant, investigator and outcome assessor blinded • Participant, investigator, outcome assessor and data-entry operator/statistician blinded	Open label clinical trial

Method of allocation concealment	Concealment of the randomization sequence is critical to prevent selection bias. Adequate allocation concealment is a pre-requisite for adequate blinding. Adequate allocation concealment methods include: • centralized (e.g. allocation by a central office unaware of subject characteristics) • pharmacy-controlled randomization • pre-numbered or coded identical containers which are administered serially to participants • on-site computer system combined with allocations kept in a locked unreadable computer file • sequentially numbered, sealed, opaque envelopes Allocation concealment that is prone to bias include • alternation • case record numbers • dates of birth or day of the week • an open list of random numbers and • any procedure that is entirely transparent before allocation



Fill as in Protocol and Click on Proceed

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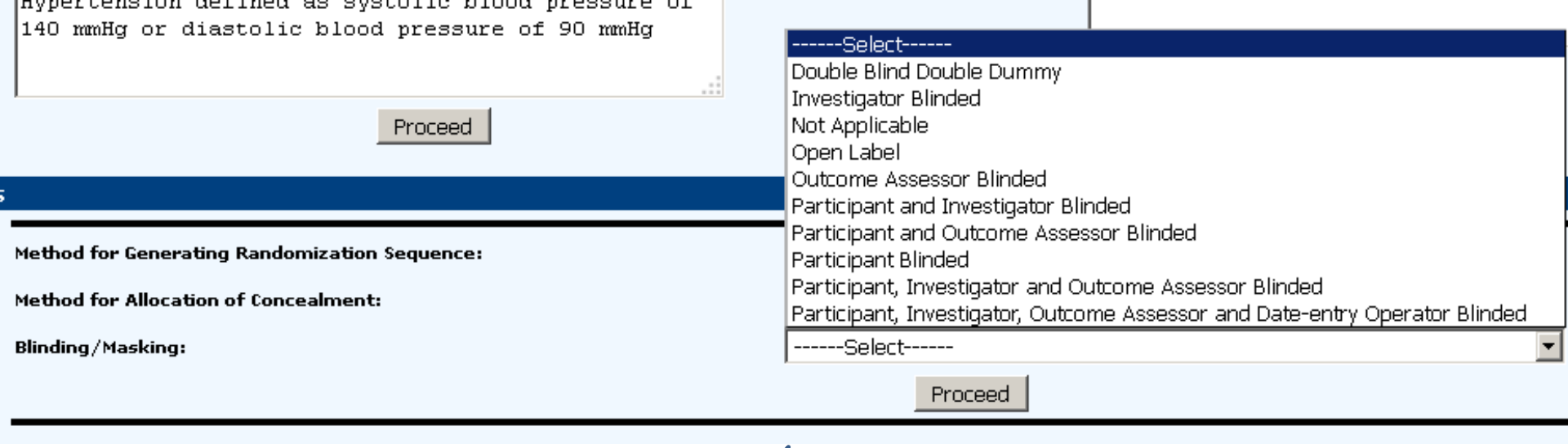
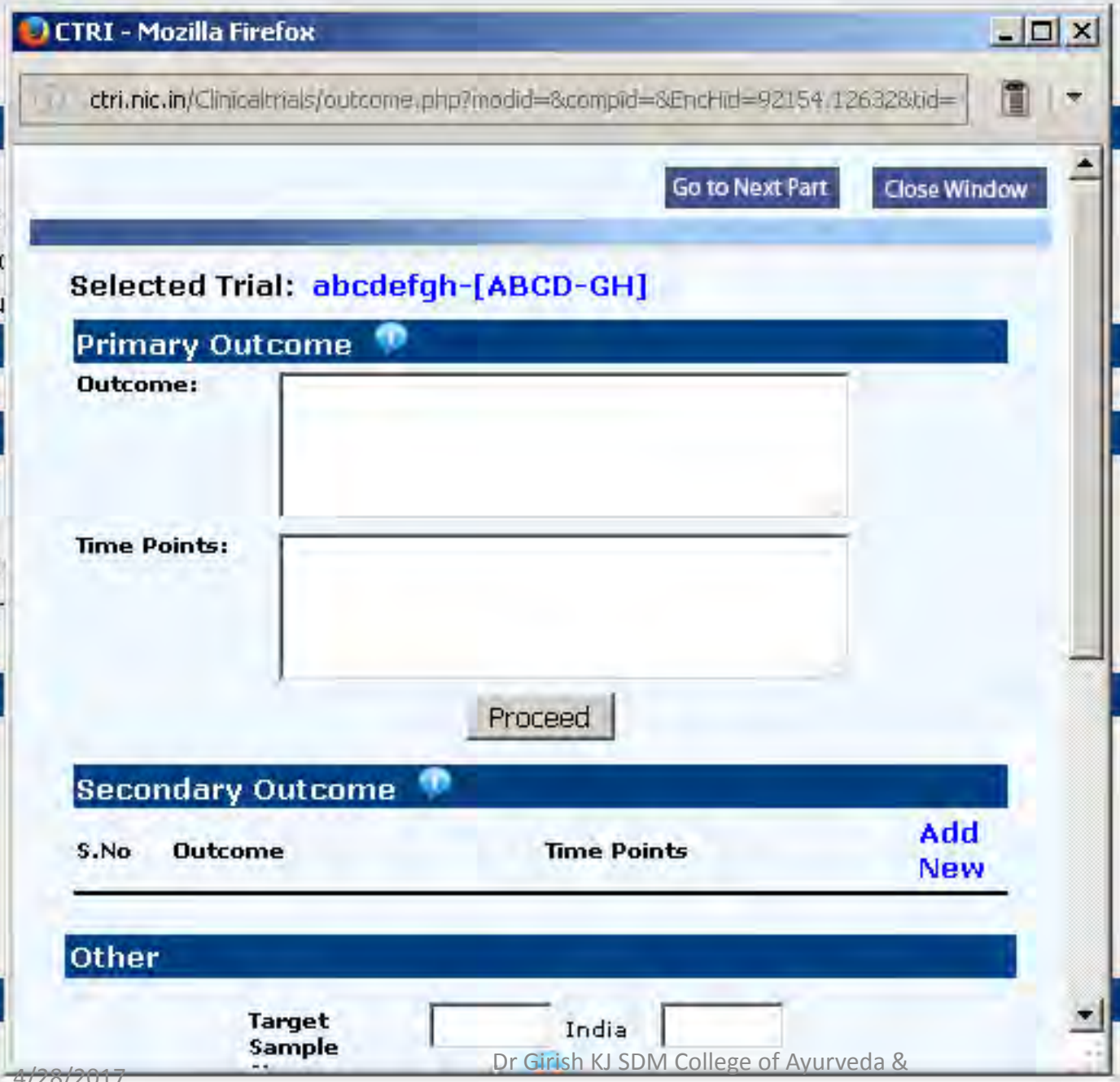


Fill as in Protocol and Click on Proceed

Part 7	
1	Primary outcome/s
2	Secondary outcome/s
3	Target sample size
4	Phase of trial
5	Date of first enrollment
6	Estimated duration of trial

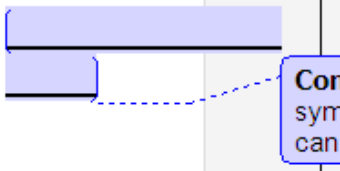
Dr Girish KJ SDM College of Ayurveda & Hospital, Hassan. girideepa@yahoo.co.in



Dr Girish KJ SDM College of Ayurveda & Hospital, Hassan. girideepa@yahoo.co.in

Primary outcome/s	Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention. The primary outcome could be the outcome used in sample size calculations, or the main outcome/s used to determine the effects of the intervention/s. Enter the names of all primary outcomes in the trial as well as the pre-specified timepoint/s of primary interest. Be as specific as possible with the metric used (e.g., "% with Beck Depression Score > 10 "rather than just "depression"). **Examples** Outcome Name: all-cause mortality, Time-points: 5 years; or Outcome Name: Mean Beck Depression Score, Time-point: 18 weeks.	Subjective criteria, Time point: **Objective Parameters:** Time point :

Secondary outcome/s	Secondary outcomes are events, variables, or experiences that are of secondary interest or that are measured at time-points of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at time-points other than those of primary interest (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: all-cause mortality at 1 year, 3 years), or may involve a different event, variable, or experience altogether (e.g., Primary outcome: all-cause mortality at 5 years; Secondary outcome: hospitalization rate at 5 years). Enter the name and time-point(s) for all secondary outcomes of clinical and/or scientific importance.



Selected Trial: abcdefg-[ACH]

Primary Outcome

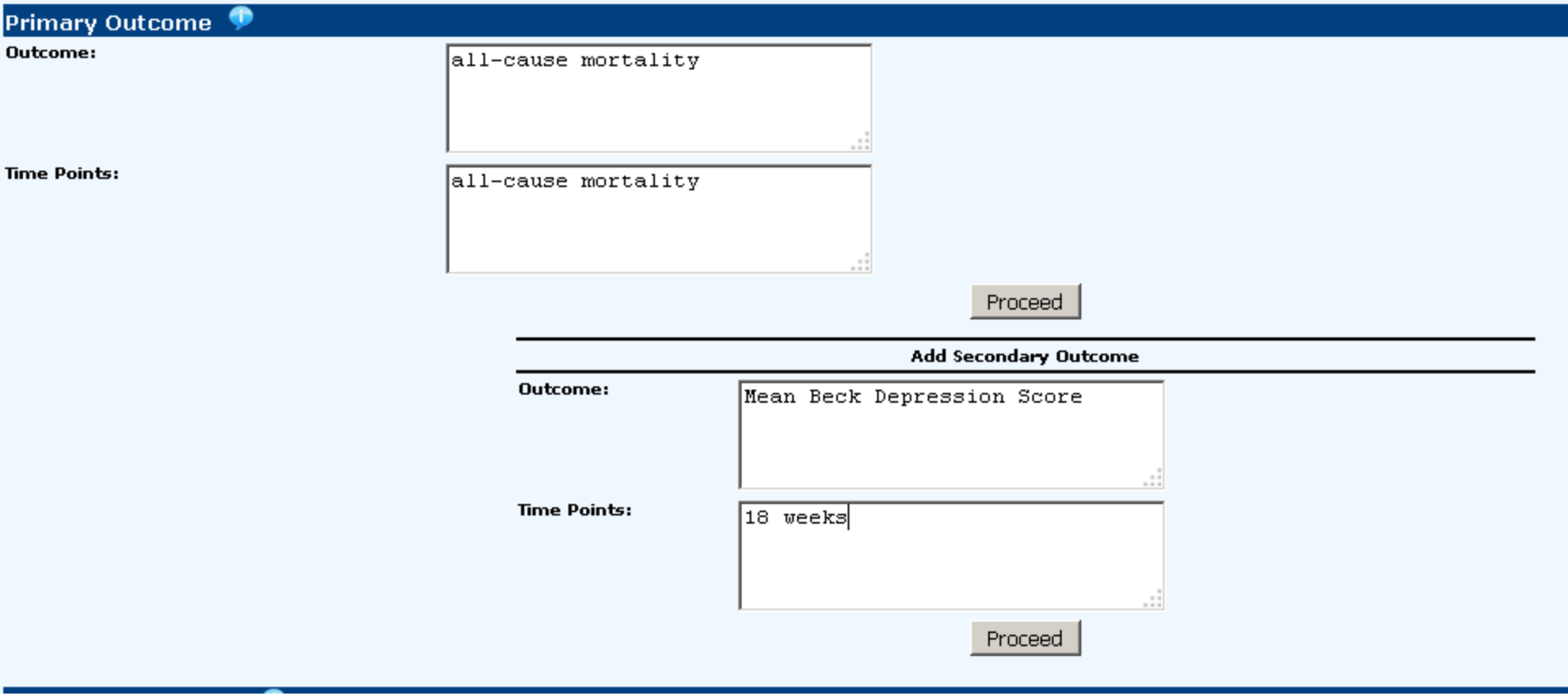
Outcome: all-cause mortality

Time Points: all-cause mortality

Proceed

Secondary Outcome

S.No	Outcome	Time Points


Primary Outcome
Outcome:
all-cause mortality
Time Points:
all-cause mortality
Proceed
Add Secondary Outcome
Outcome:
Mean Beck Depression Score
Time Points:
18 weeks
Proceed

Primary Outcome

Outcome:

all-cause mortality

Time Points:

all-cause mortality

Proceed

Secondary Outcome

S.No	Outcome	Time Points
1	Mean Beck Depression Score	18 weeks

Target sample size	Total number of participants that the trial plans to enroll. **For global/multi-country trials**, enter both Total sample size and Target sample size from India. This is a numbers only field. **Example** Target sample size **120** India **500** Total **For trials being conducted only in India**, target sample should be same under both columns Target sample size **120** India **120** Total	Target sample size Indi Total

Phase of trial	Phases of investigation, usually applied to a drug trial Phase 1: includes initial study to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing does, and to gain early evidence of effectiveness; may include healthy participants and/or patients (such as those testing anticancer or anti-HIV drugs) . Trials are often dose ranging trials which are done to determine the maximum dose of a new medication that can be safely given to a patient. Phase 1 / Phase 2: for trials that are at a combined stage of phases 1 and 2 Phase 2: includes controlled clinical study conducted to evaluate/test the effectiveness of a new drug/medication or intervention for a particular indication or indications in patients with the disease or condition being studied and to determine the common short-term side effects and risks Phase 2 / Phase 3: for trials that are at a combined stage of phases 2 and 3 Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been	Phase 2 / phase 3

Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of a new drug/medication or intervention, including possible adverse reactions. It is also to provide an adequate basis for physician labeling

Phase 3 /Phase 4: For trials that are at a combined stage of phases 3 and 4

Phase 4: Studies (other than routine surveillance) performed after drug is marketed and is related to the approved indication.
Trials are done to monitor the toxicity, risks, utility, benefits and optimal use after the efficacy of the drug/medication or intervention has been proven.

N/A (Not applicable): This selection is for a non-drug trial, BA/BE trial.

Post marketing surveillance: Routine surveillance trials after marketing approval

Example

Date of first enrollment	Select anticipated or actual date of enrollment of the first participant from the calendar. **For global/multi-country trials**, both global trial start date as well as start date in India should be mentioned. **Example** **date of first enrollment** 02/05/2009 **India** 15/06/2010 **Global**
Estimated duration of trial	Specify the expected time duration of trial, starting from enrollment of first patient to final submission of report.

Target Sample Size: 30 India 30 Total

Phase of Trial: Phase 2/ Phase 3

Date of First Enrollment: 02/05/201 India Global

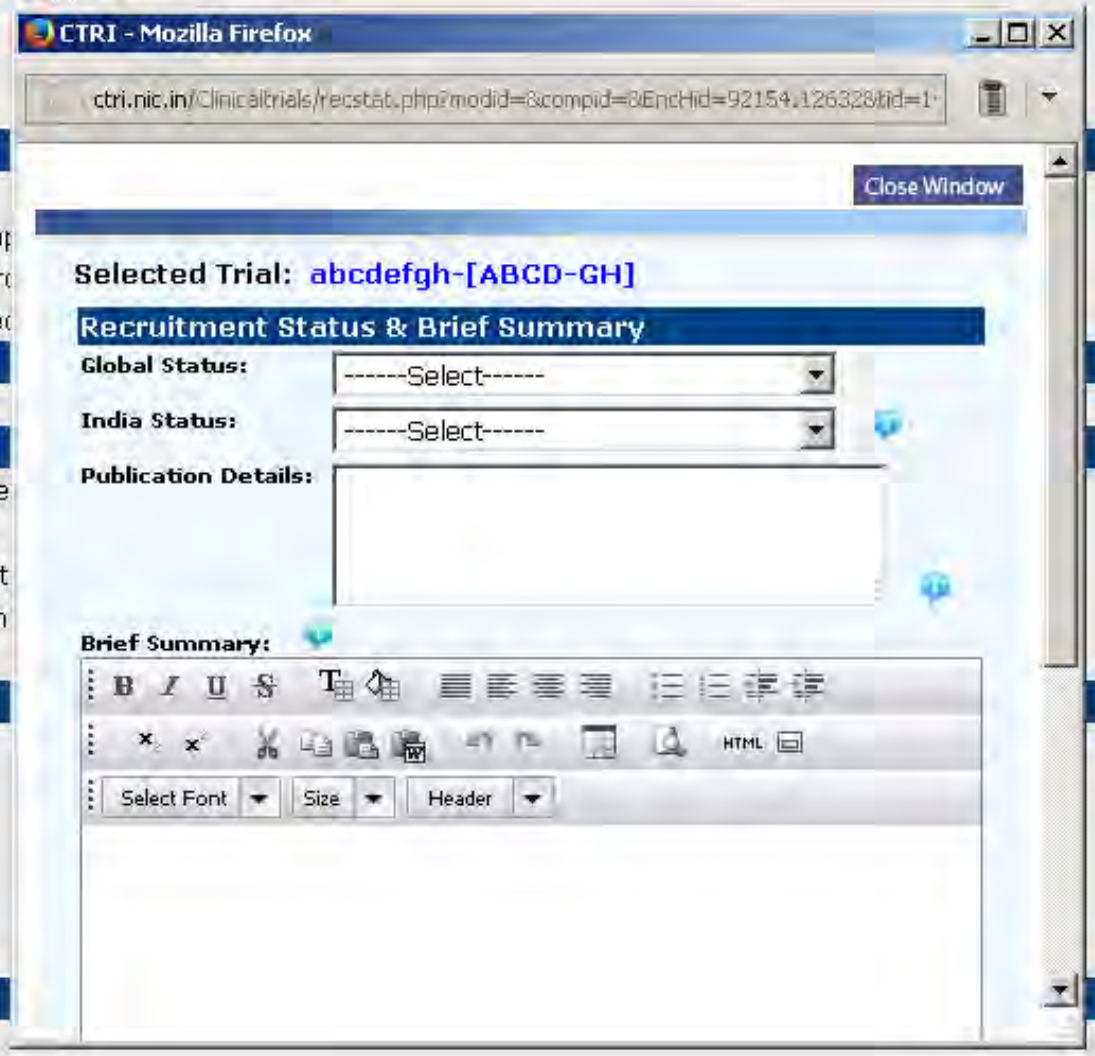
Estimated Duration: 2 Year(s) 0 Month(s) 0 Day(s)

Proceed

Part B (Includes Trial Submission link)

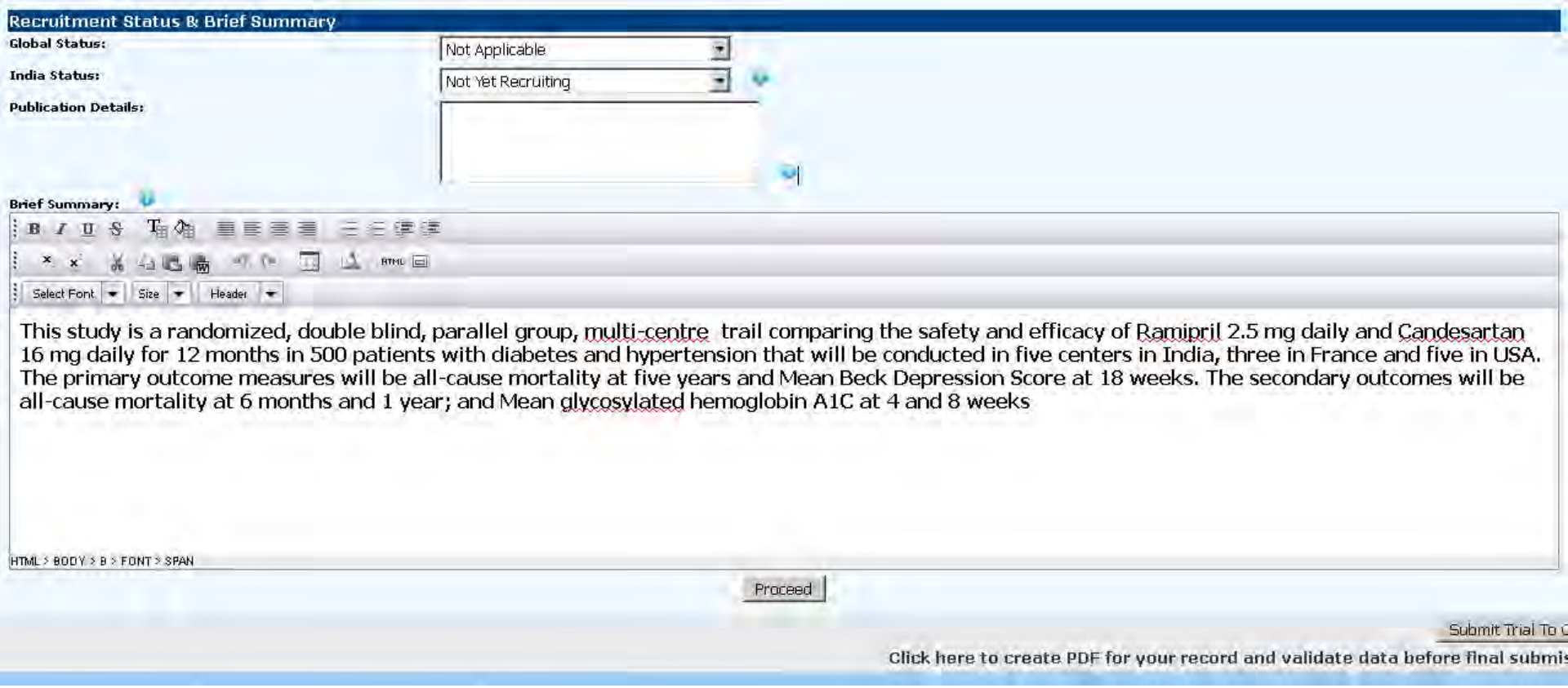
1	Recruitment status of trial
2	Brief Summary
3	Publication

1	Source/s of monetary or material support
2	Primary sponsor
3	Secondary Sponsor
4	Countries of recruitment
Part 4	
1	Site/s of study
2	Name of Ethics Committee and ap
3	Regulatory clearance obtained fr
4	Health condition/problems studie
Part 5	
1	Study Type
Part 6	
1	Intervention and comparator age
2	Inclusion & Exclusion Criteria
3	Method of generating randomizat
4	Method of allocation concealmen
5	Blinding/masking
Part 7	
1	Primary outcome/s
2	Secondary outcome/s
3	Target sample size
4	Phase of trial
5	Date of first enrollment
6	Estimated duration of trial
Part 8 (Includes Trial Submission link)	
1	Recruitment status of trial
2	Brief Summary



trial	
Recruitment status of trial	Indicate status of trial. **For global/multi-country trials** enter status of global arm as well as Indian arm o **Not Yet Recruiting**: Yet to initiate patient enrolment o **Open to Recruitment**: Participants are currently being recruited and enrolled o **Suspended**: There is a temporary halt in recruitment and enrolment but potentially will resume o **Completed**: Closed to recruitment of participants and data analysis complete • **Closed to recruitment of participants**: Follow- up continuing • **Other(Terminated)**: Recruiting or enrolling participants has halted and will not resume

Brief Summary	Short description of the primary purpose of the protocol, including a brief statement of the study hypothesis. Include publication/s details (link/reference), if any. **Example:** This study is a randomized, double blind, parallel group, multi-centre trail comparing the safety and efficacy of Ramipril 2.5 mg daily and Candesartan 16 mg daily for 12 months in 500 patients with diabetes and hypertension that will be conducted in five centers in India, three in France and five in USA. The primary outcome measures will be all-cause mortality at five years and Mean Beck Depression Score at 18 weeks. The secondary outcomes will be all-cause mortality at 6 months and 1 year; and Mean glycosylated hemoglobin A1C at 4 and 8 weeks.


Recruitment Status & Brief Summary
Global Status:
Not Applicable
India Status:
Not Yet Recruiting
Publication Details:
Brief Summary:
Select Font
Size
Header
This study is a randomized, double blind, parallel group, multi-centre trail comparing the safety and efficacy of Ramipril 2.5 mg daily and Candesartan 16 mg daily for 12 months in 500 patients with diabetes and hypertension that will be conducted in five centers in India, three in France and five in USA. The primary outcome measures will be all-cause mortality at five years and Mean Beck Depression Score at 18 weeks. The secondary outcomes will be all-cause mortality at 6 months and 1 year; and Mean glycosylated hemoglobin A1C at 4 and 8 weeks
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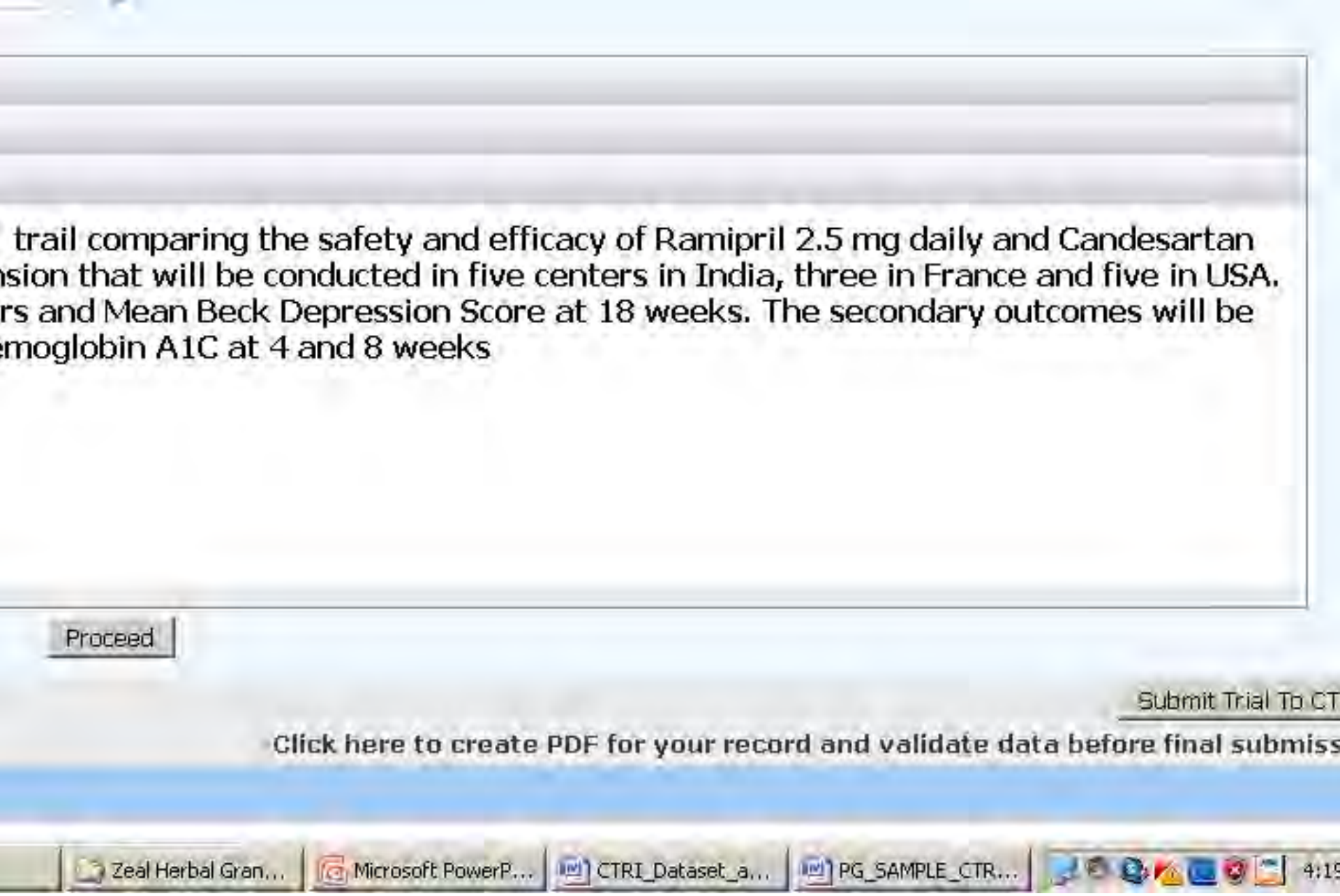
Submit Trial To
Click here to create PDF for your record and validate data before final submis


trail comparing the safety and efficacy of Ramipril 2.5 mg daily and Candesartan
sion that will be conducted in five centers in India, three in France and five in USA.
rs and Mean Beck Depression Score at 18 weeks. The secondary outcomes will be
moglobin A1C at 4 and 8 weeks
Proceed
Submit Trial To CT
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Microsoft PowerP...
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PG_SAMPLE_CTR...
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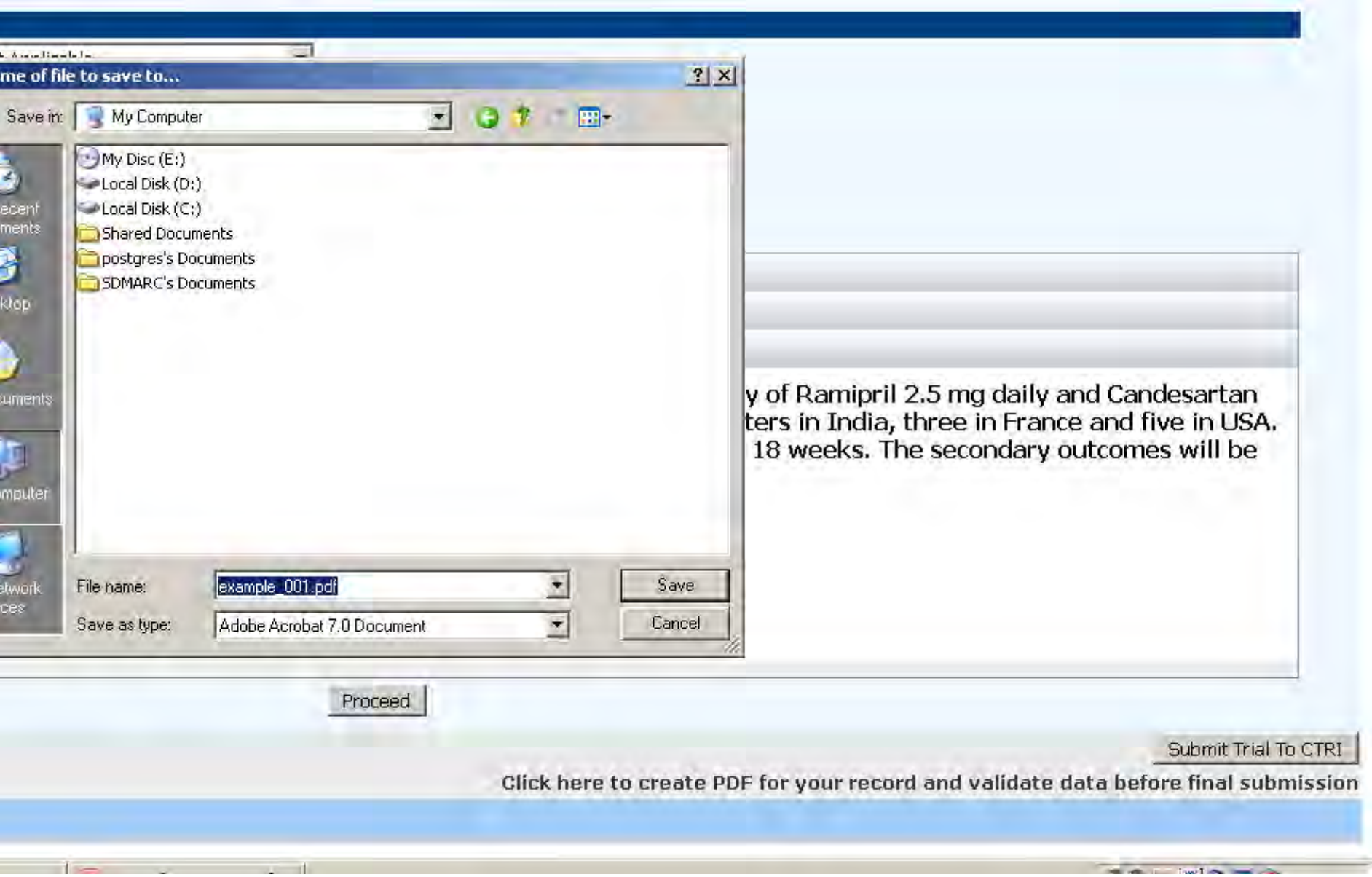
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Save in:
My Computer
My Disc (E:)
Local Disk (D:)
Local Disk (C:)
Shared Documents
postgres's Documents
SDMARC's Documents
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Save as type:
Adobe Acrobat 7.0 Document
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y of Ramipril 2.5 mg daily and Candesartan
ters in India, three in France and five in USA.
18 weeks. The secondary outcomes will be
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Submit Trial To CTRI
Click here to create PDF for your record and validate data before final submission

example_001.pdf - Adobe Reader

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1 / 3 143%

CLINICAL TRIALS REGISTRY - INDIA
NATIONAL INSTITUTE OF MEDICAL STATISTICS
(INDIAN COUNCIL OF MEDICAL RESEARCH)

Pendi
CTRI W

Clinical Trial Details (PDF Generation Date :- Fri, 15 Apr 2016 08:55:10 GMT)

CTRI Number	Pending -
Last Modified On	
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Randomized, Parallel Group Trial
Public Title of Study	abcde
Scientific Title of Study	abcdefg

Secondary IDs if Any	**Secondary ID**	**Identifier**

	Details of Principal Investigator
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	
Name	DR XYZ
Designation	PROFESSOR DEPARTMENT OF KA

CTRI - Mozilla Firefox

ctri.nic.in/Clinicaltrials/rmainde[redacted]

FULL DETAILS (Read-only) -> **Click Here to Create PDF for Current Dataset of Trial**

CTRI No	**Pending**
Acknowledgement Number	REF/2[redacted]
Last Modified On:	1[redacted]
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Single Arm Trial
Public Title of Study Clarification(s) with Reply Modification(s)	Clinical Study on t[redacted]
Scientific Title of Study	Clinical Study [redacted]
Acronym	
Secondary IDs if Any	**Secondary ID**: NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	**Name**: [redacted] **Designation**: [redacted] **Affiliation**: Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospi **Address**: Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospi Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospi Hassan KARNATAKA 573201 India **Phone**: [redacted] **Fax**: **Email**:

(Indian Council of Medical Research)

nd Hospital Hassan Karnataka 30/03/2016

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als | General Query | Edit Profile

Total Trials	**1**
Under Entry Stage	1
Under Review Stage	0
Registered Trials	0
Terminated/Suspended Trials	0

Add New Trial

Trials Under Entry/ Review

	Scientific Title	Acronym	Secondary ID	View Details	Select
	abcdefg	ACH		Full Details	Update || Delete

Trial Clarification/Modification | Registered Trials | General Query | Edit Profile

Total Trials	**1**
Under Entry Stage	1
Under Review Stage	0
Registered Trials	0
Terminated/Suspended Trials	0

Add New Trial

Trials Under Entry/ Review

S.No.	Reference No	CTRI No	Scientific Title	Acronym	Secondary ID	View Details	Select
1	Pending	Pending	abcdefg	ACH		Full Details	Update || Delete

Trials sent back after review by CTRI

CTRI No.	REF No.	SENT BACK ON	PROTOCOL No.	TRIAL TYPE	CLARIFICATION

After you upload your clinical / survey study you may get messages / clarifications to correct various aspects of your study.

- For Example.....

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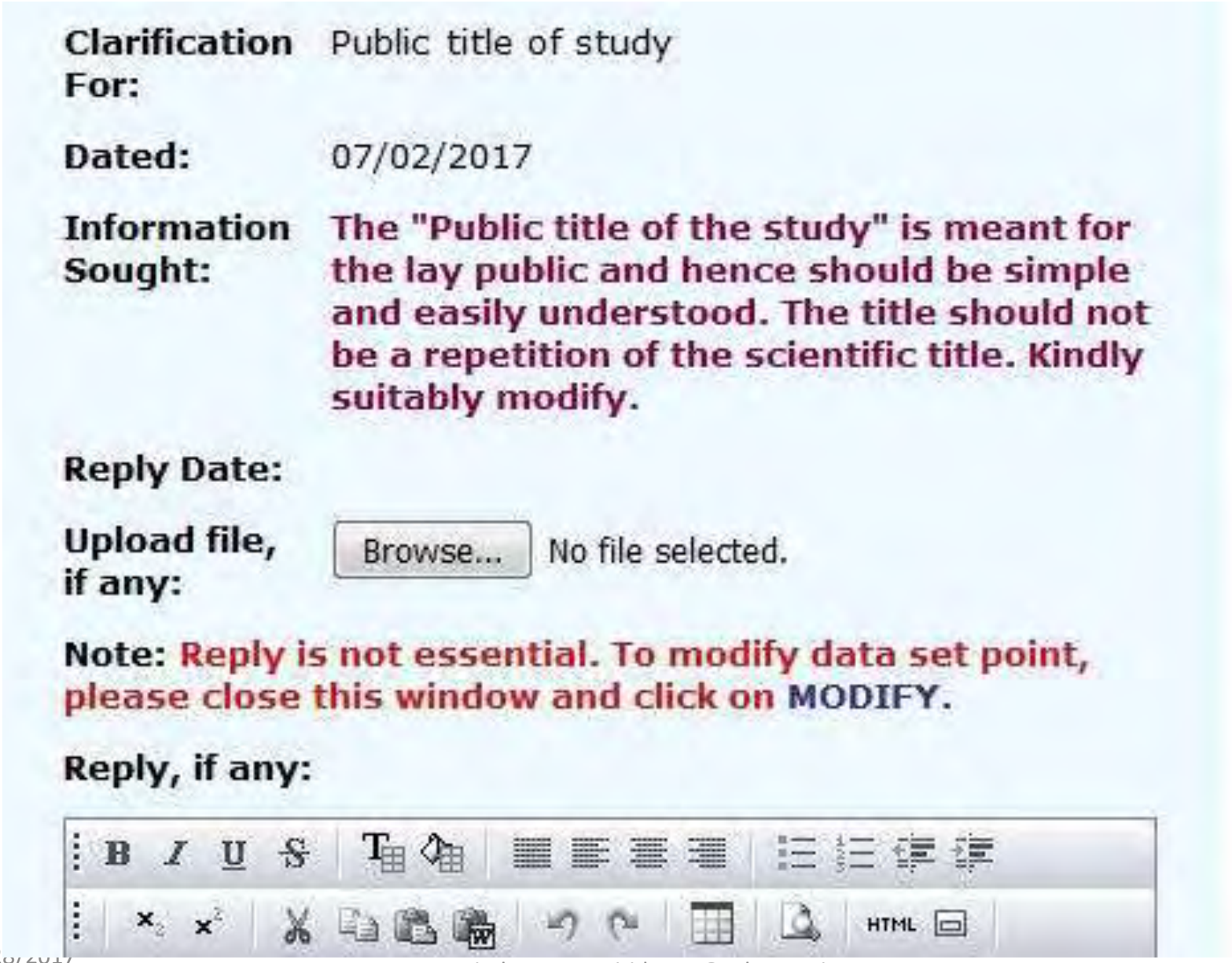
	Acronym	Secondary ID	View Details	Select
anules in the		NIL[NIL]	Full Details	Submitted to CTRI on 30/04/2016 Last Submitted On: 15/03/2017

ROTOCOL No.	TRIAL TYPE	CLARIFICATION

Under Public title of study



Scientific title of study

Clarification For: Scientific title of study

Dated: 07/02/2017

Information Sought: AGPT does not appear to be trial acronym, if there is no designated trial acronym pl leave the field blank

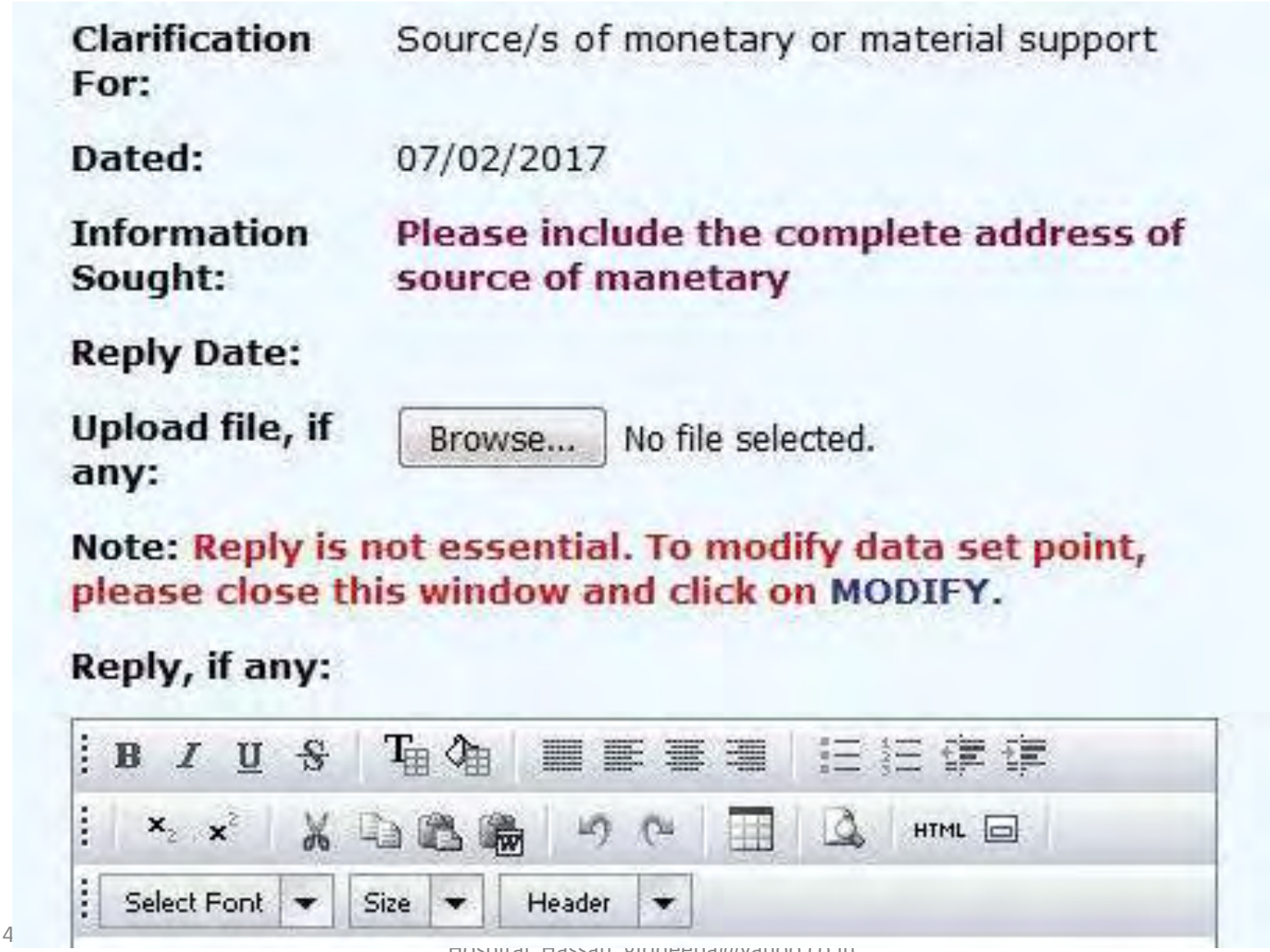
Reply Date:

Upload file, if any: Browse... No file selected.

Note: Reply is not essential. To modify data set point, please close this window and click on MODIFY.

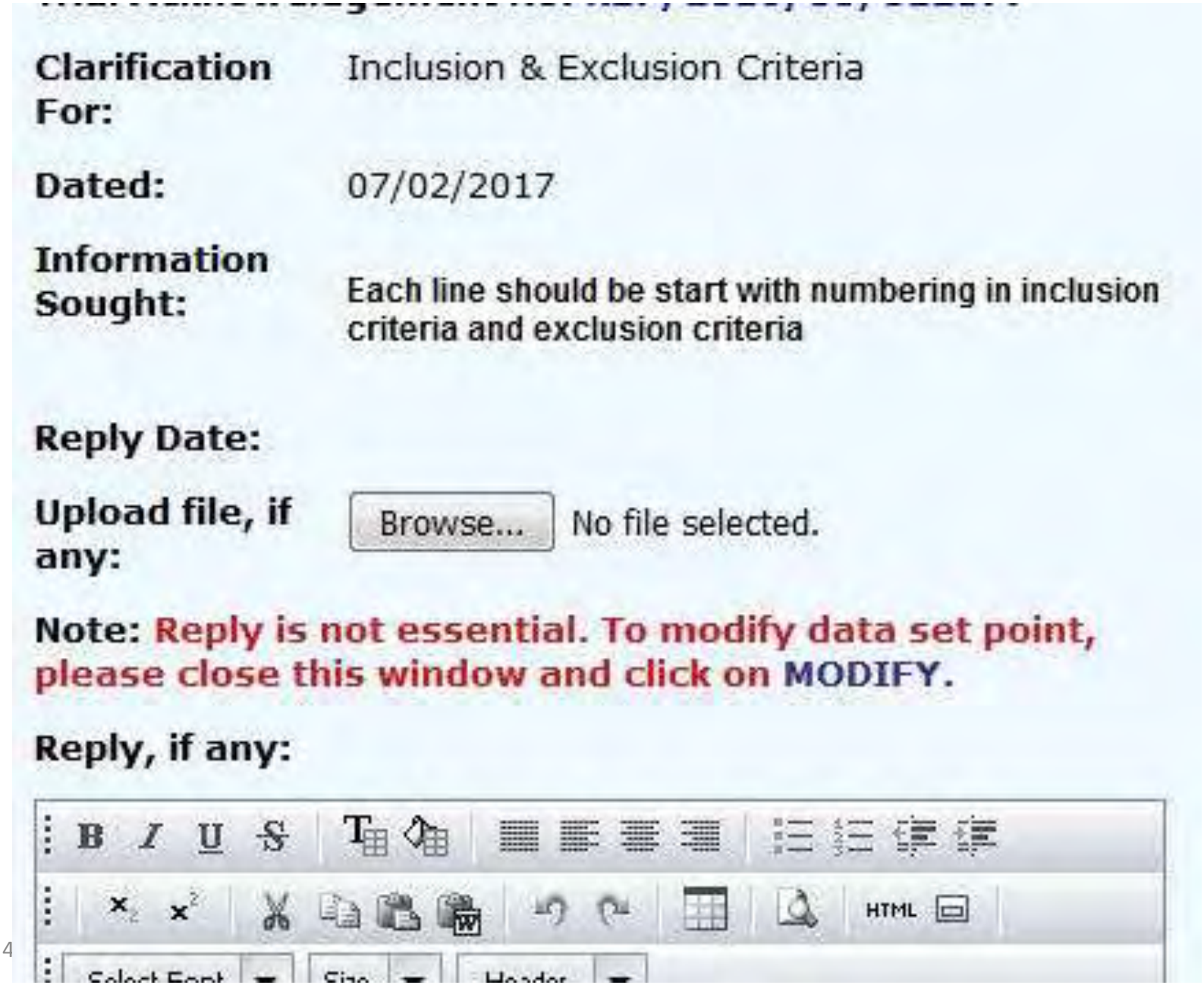
Reply, if any:

Source of monetary fund



Hospital, Hassan. gindeepa@yahoo.co.in

Inclusion and Exclusion Criteria



Site of Study

Clarification For: Site/s of study

Dated: 07/02/2017

Information Sought: Under NAME OF SITE please mention only name of the hospital and under SITE ADDRESS please mention the room no, department and division.

Reply Date:

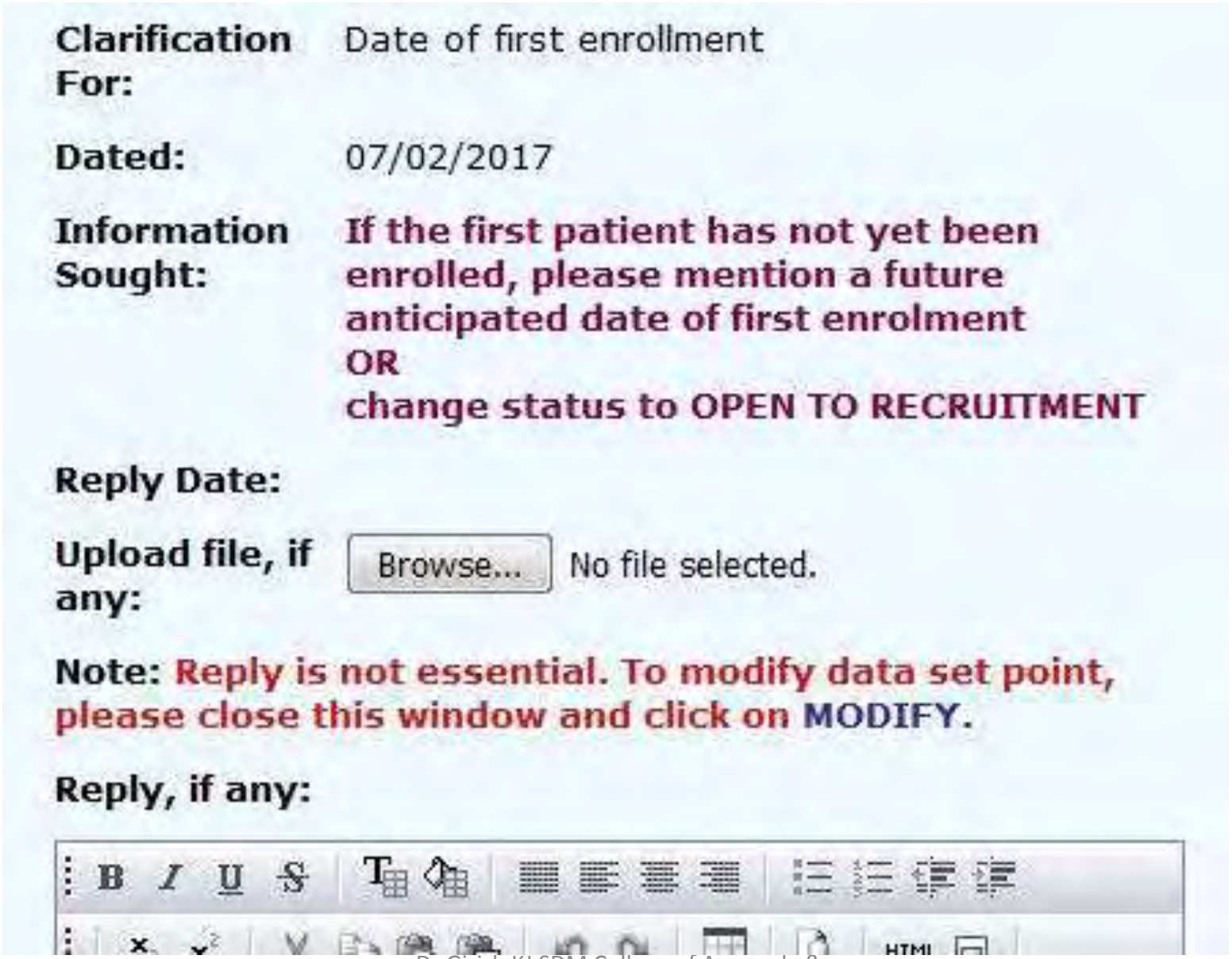
Upload file, if any: Browse... No file selected.

Note: Reply is not essential. To modify data set point, please close this window and click on MODIFY.

Reply, if any:

Hospital, Hassan. gindeepa@yahoo.co.in

Date of First Enrollment



Recruitment Status of Trial

Publication

Clarification For: Publication

Dated: 07/02/2017

Information Sought: **Please note, publication details may also be provided which pertain and arise directly out of this trial, if there are "none yet" the same be mentioned**

Reply Date:

Upload file, if any: Browse... No file selected.

Note: Reply is not essential. To modify data set point, please close this window and click on MODIFY.

Reply, if any:

Name of Ethic Committee and Approval Status

Clarification For: Name of Ethics Committee and approval status

Dated: 06/03/2017

Information Sought: Uploaded approval is not viewable

Submission of APPROVAL is mandatory prior to trial registration

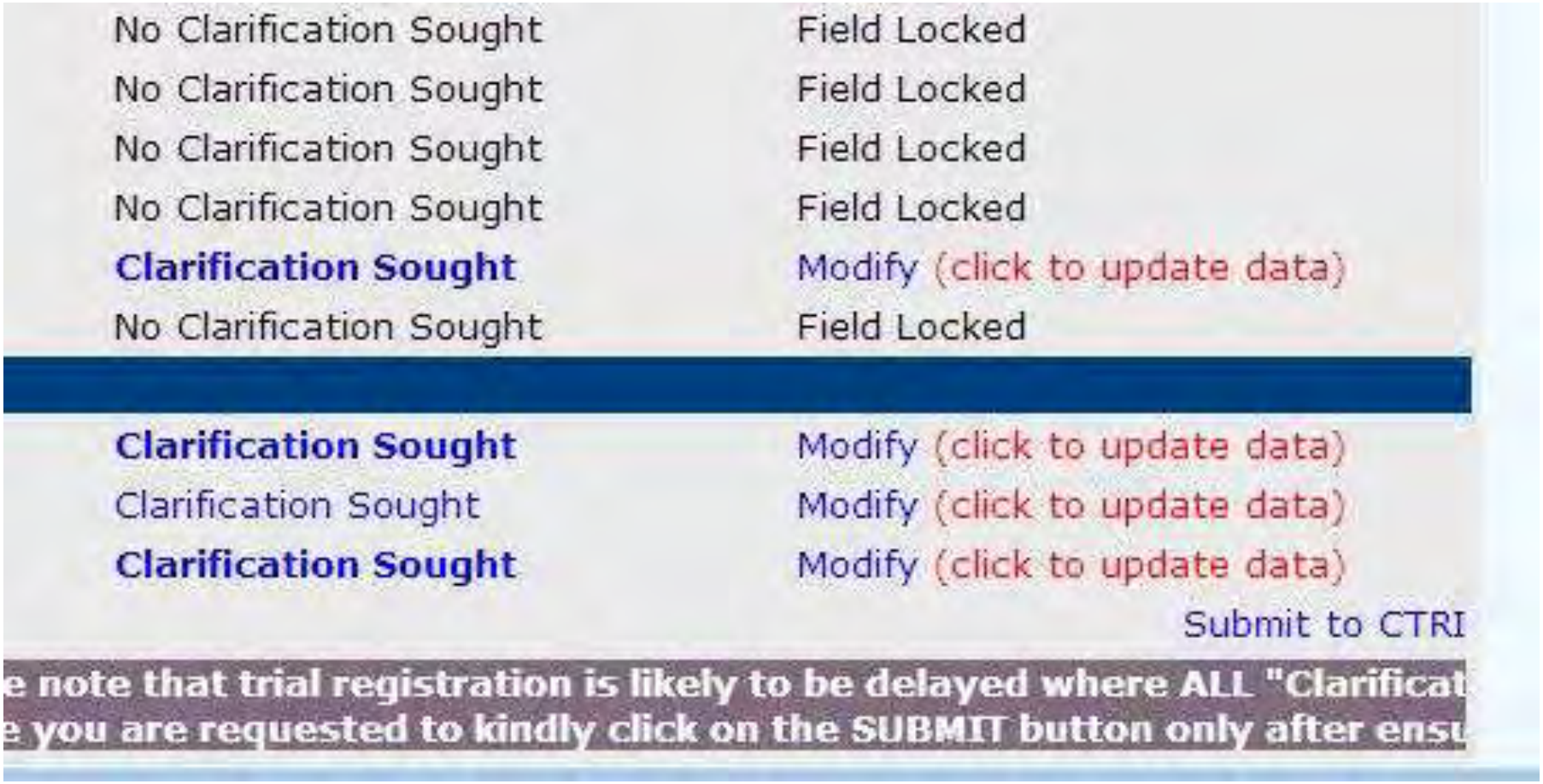
Please upload approvals strictly as per format spelt out below (after choosing approval status as APPROVED):

- Only MS-WORD or PDF format should be uploaded.
- In case this is a JPEG file, pl copy past the image on to a WORD file save it and then upload it
- File names should not contain blank spaces or dots eg EC APPROVAL.1, please change this file name to EC_APPROVAL1 or ECapproval1
- Uploaded files should not be more than 1 MB.
- After uploading file, please view the "link" to confirm that it is viewable

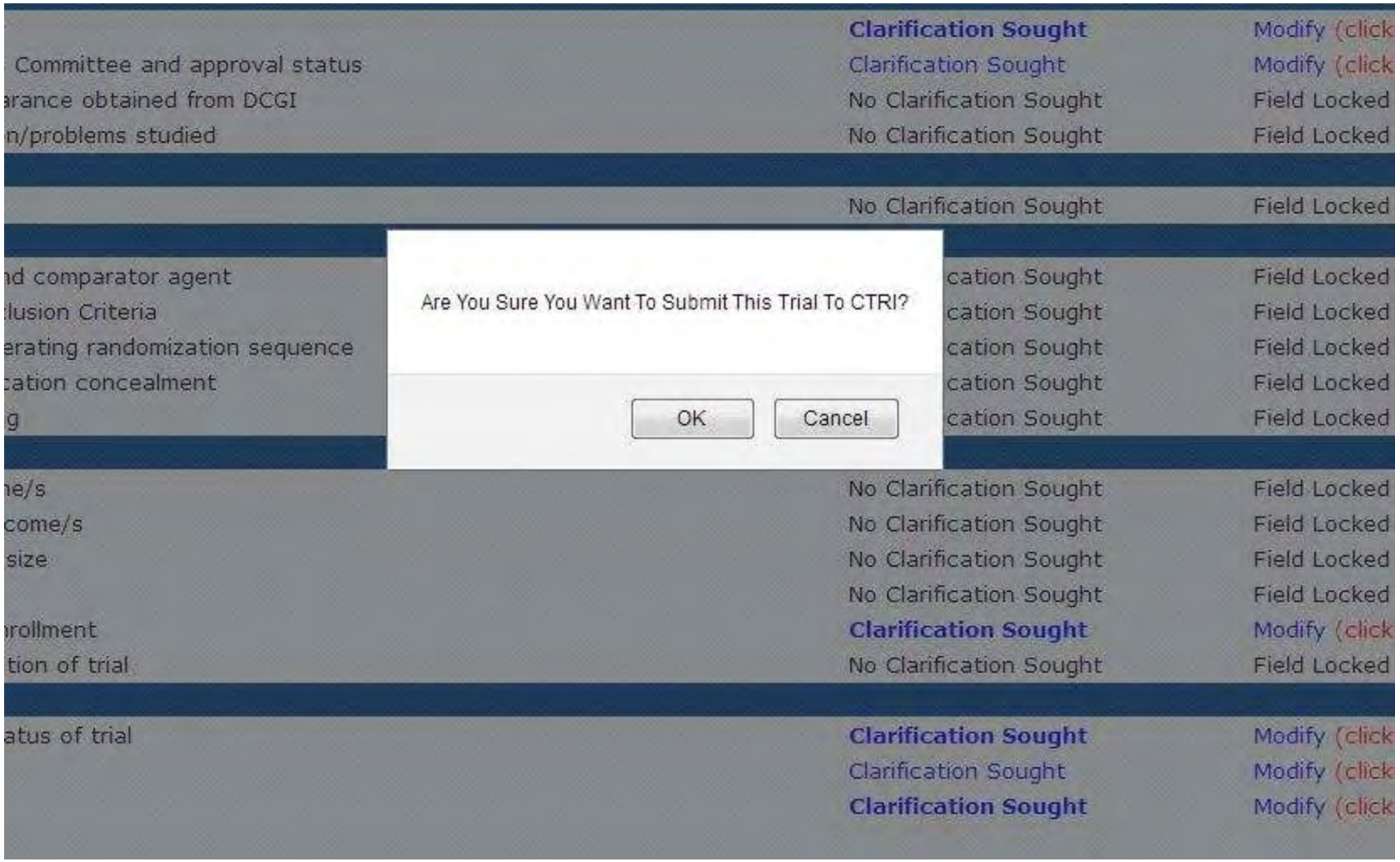
Brief Summary

Clarification For:	Brief Summary
Dated:	06/03/2017
Information Sought:	In the brief summary please provide English equivalent of Ayurvedic terms used. Please also provide brief description of Ayurvedic processes and composition/constituents of Ayurvedic agents to enable better understanding of study.
Reply Date:	
Upload file, if any:	Browse... No file selected.

After doing correction… you have to submit the Data to CTRI



Submit the data



After several rounds of clarifications….

- After few days, CTRI will issue CTRI No.. Which may be used during
- your submitting the protocol to funding agency
- Publication
- Etc..

Thank you!

- **For any help contact me on Dr Girish KJ, drgirishkj@sdmcahhassan.org girideepa@yahoo.co.in, 09448646855**
- **Created as on 28, Apr, 2017**