TRAINING SESSION:

ENHANCED PRISM E-SERVICES

OTHER CLINICAL TRIALS SUBMISSIONS
TRACK & ENQUIRE @ PRISM

OUTLINE

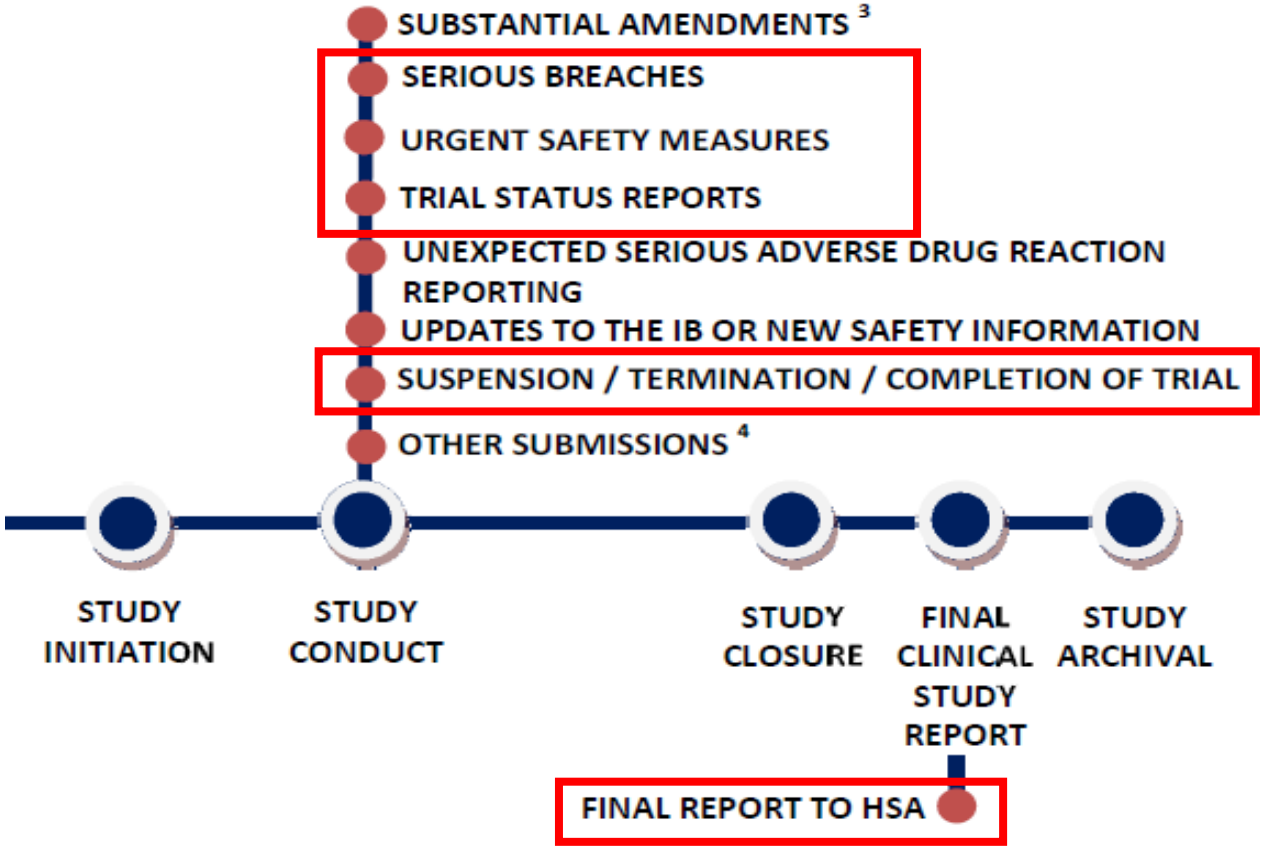
Other PRISM Submissions

- Serious breaches
- Urgent safety measures
- Trial status report
- Final study report

PRISM Functions

- Track @ PRISM
- Enquire @ PRISM

REGULATORY SUBMISSIONS DURING TRIAL CONDUCT



[4] Other submissions include changes to Clinical Research Material Notification, changes to information in the Clinical Trials Register or changes to the regulatory status of trial in other countries.

SERIOUS BREACHES &

URGENT SAFETY MEASURES

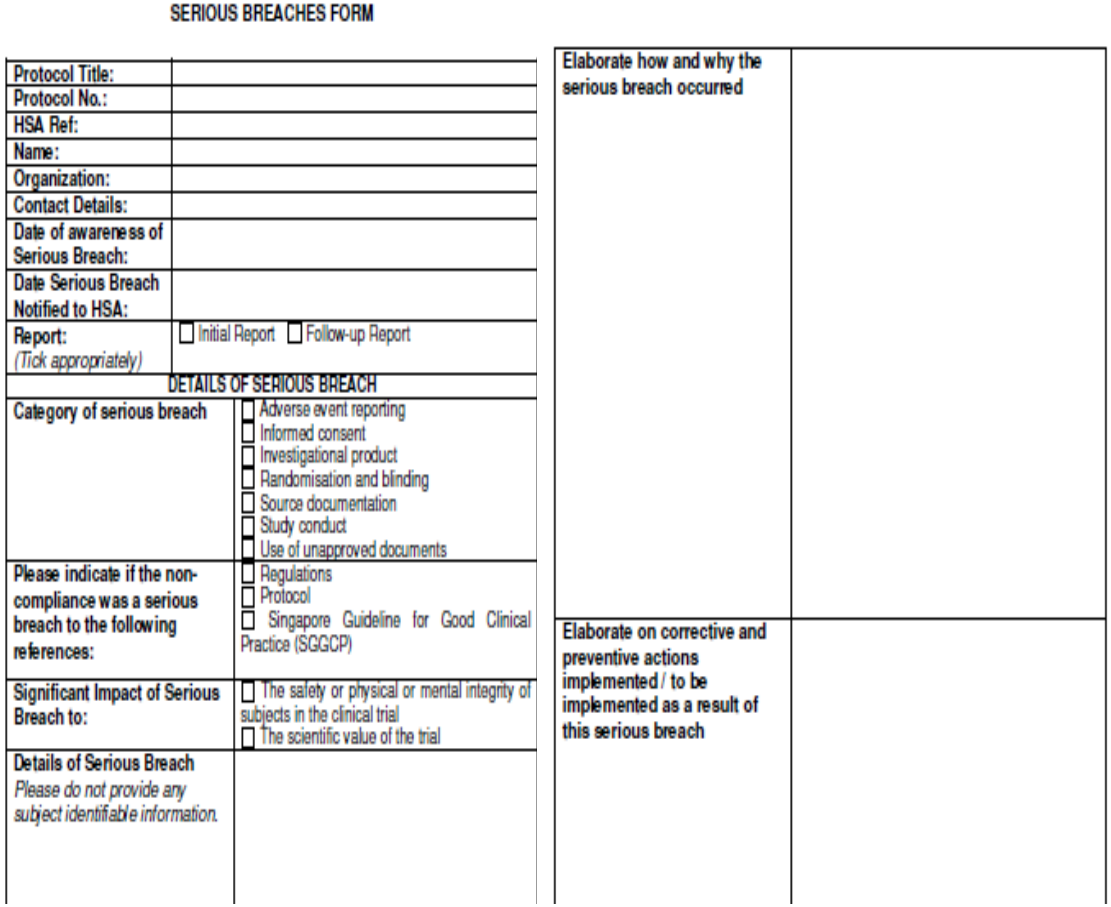
SERIOUS BREACHES

- A serious breach is a deviation which is likely to affect to a significant degree:
  a) The safety or physical or mental integrity of any subjects in a clinical trial; or
  b) The scientific value of the clinical trial.

- Any serious breach of the principles of GCP, trial protocol or clinical trials regulations should be notified to HSA.

- Sponsor to notify HSA in writing as soon as possible and in any event not later than 7 days after becoming aware of the breach

SERIOUS BREACHES



SERIOUS BREACHES FORM

Protocol Title:	
Protocol No.:	
HSA Ref:	
Name:	
Organization:	
Contact Details:	
Date of awareness of Serious Breach:	
Date Serious Breach Notified to HSA:	
Report: *(Tick appropriately)*	☐ Initial Report ☐ Follow-up Report

DETAILS OF SERIOUS BREACH

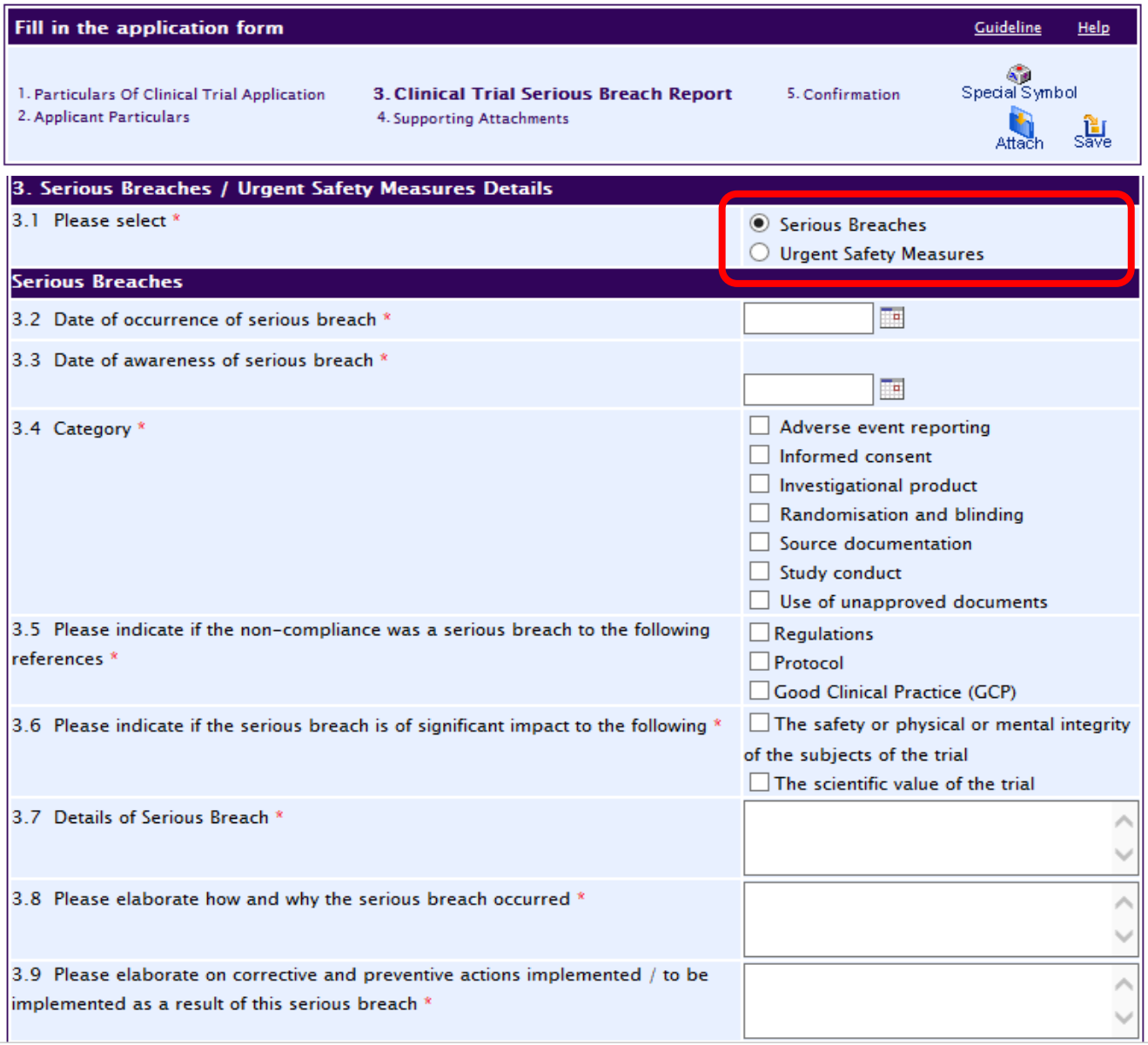
Category of serious breach	☐ Adverse event reporting ☐ Informed consent ☐ Investigational product ☐ Randomisation and blinding ☐ Source documentation ☐ Study conduct ☐ Use of unapproved documents
Please indicate if the non-compliance was a serious breach to the following references:	☐ Regulations ☐ Protocol ☐ Singapore Guideline for Good Clinical Practice (SGGCP)
Significant Impact of Serious Breach to:	☐ The safety or physical or mental integrity of subjects in the clinical trial ☐ The scientific value of the trial
Details of Serious Breach *Please do not provide any subject identifiable information.*	

Elaborate how and why the serious breach occurred	
Elaborate on corrective and preventive actions implemented / to be implemented as a result of this serious breach	

From 1st Nov 2016 onwards,

Submission via PRISM

SERIOUS BREACHES



Fill in the application form Guideline Help

1. Particulars Of Clinical Trial Application
2. Applicant Particulars
3. **Clinical Trial Serious Breach Report**
4. Supporting Attachments
5. Confirmation

Special Symbol | Attach | Save

3. Serious Breaches / Urgent Safety Measures Details

3.1 Please select *
- (•) Serious Breaches
- ( ) Urgent Safety Measures

Serious Breaches

3.2 Date of occurrence of serious breach *

3.3 Date of awareness of serious breach *

3.4 Category *
- [ ] Adverse event reporting
- [ ] Informed consent
- [ ] Investigational product
- [ ] Randomisation and blinding
- [ ] Source documentation
- [ ] Study conduct
- [ ] Use of unapproved documents

3.5 Please indicate if the non-compliance was a serious breach to the following references *
- [ ] Regulations
- [ ] Protocol
- [ ] Good Clinical Practice (GCP)

3.6 Please indicate if the serious breach is of significant impact to the following *
- [ ] The safety or physical or mental integrity of the subjects of the trial
- [ ] The scientific value of the trial

3.7 Details of Serious Breach *

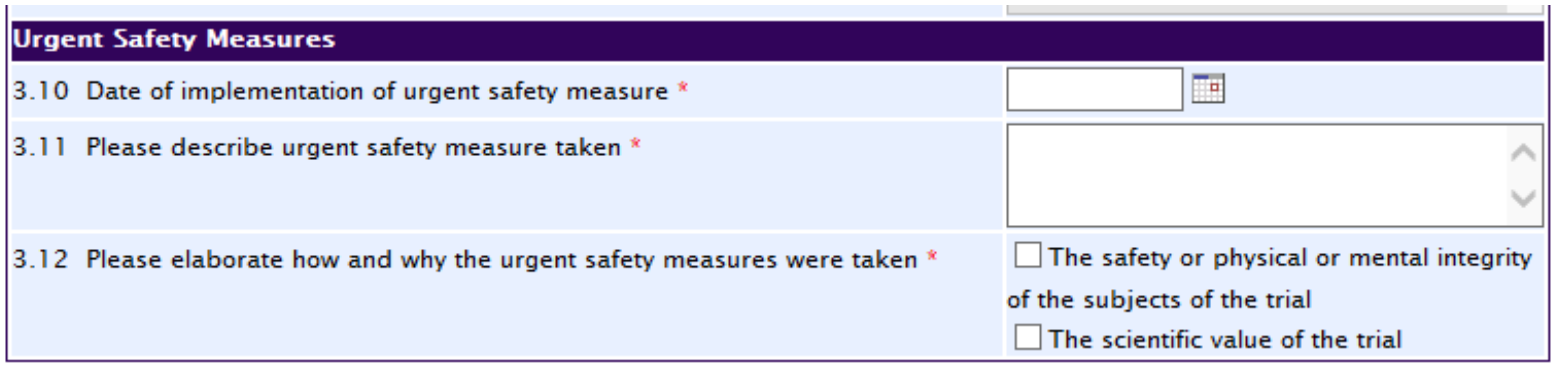
3.8 Please elaborate how and why the serious breach occurred *

3.9 Please elaborate on corrective and preventive actions implemented / to be implemented as a result of this serious breach *

URGENT SAFETY MEASURES

- In order to protect any subject against any immediate hazard to the health or safety of the subject, the sponsor and any investigator of the clinical trial may take appropriate urgent safety measures.

- Sponsor to notify HSA in writing as soon as possible and in any event not later than 7 days after the date measure is taken



Urgent Safety Measures	
3.10 Date of implementation of urgent safety measure *	
3.11 Please describe urgent safety measure taken *	
3.12 Please elaborate how and why the urgent safety measures were taken *	☐ The safety or physical or mental integrity of the subjects of the trial ☐ The scientific value of the trial

TRIAL STATUS REPORT

TRIAL STATUS REPORT

During Trial Conduct

- Sponsor to submit trial status report to HSA every 6 months starting from CTA authorisation, CTN acceptance or CTC issuance, until trial conclusion or termination.

- Immediately or within such other time as required by HSA.

Reminder email:
Every 6 months from the CTA/CTN/CTC approval/ acceptance date.

TRIAL STATUS REPORT

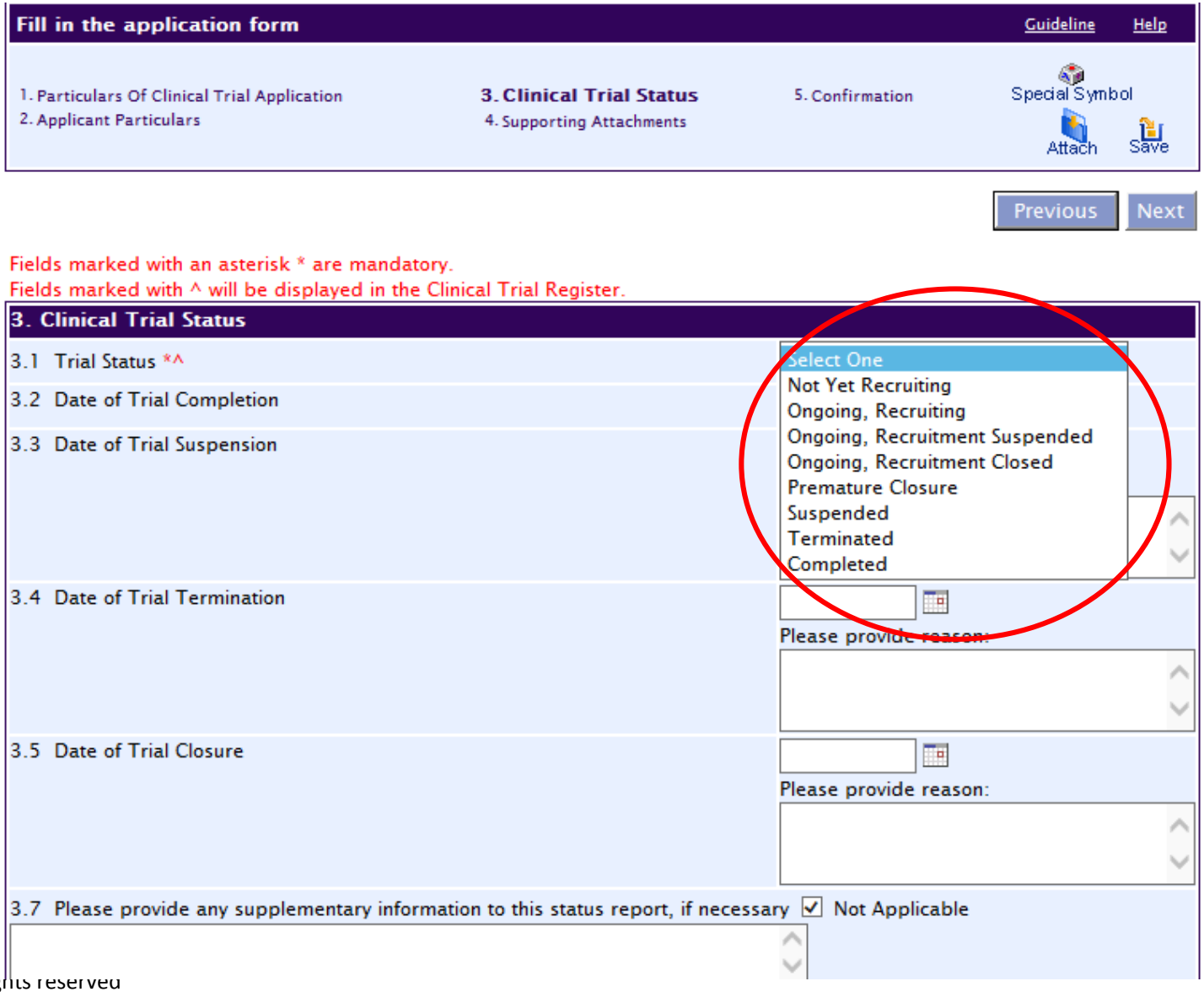
Trial Suspension or Termination

- Sponsor to notify HSA (via trial status report) within 15 days after date of suspension or termination.

Trial Conclusion

- Sponsor to notify HSA (via trial status report) within 30 days of trial conclusion.

TRIAL STATUS REPORT



TRIAL STATUS (LOCAL)

Field	Definition
Not yet recruiting	The local trial site(s) has/have not commenced recruiting subjects into the clinical trial.
Ongoing, recruiting	The local trial site(s) has/have commenced recruiting subjects into the clinical trial.
Ongoing, recruitment suspended	The recruitment has been suspended. However, the enrolled subjects are still continuing with the study procedures.
Ongoing, recruitment closed	The recruitment has been closed. However, the enrolled subjects are still continuing with the study procedures.
Premature Closure	The local trial site(s) was/were closed prematurely as **no subjects were screened into the clinical trial**.
Suspended	The clinical trial has been suspended. All screening and enrollment activities should be suspended. Please notify the IRB and HSA if existing subjects are to continue with the study procedures.
Terminated	The clinical trial has been terminated. All screening and enrollment activities should be terminated; and existing subjects **should not** continue with the study procedures.
Completed	Study completion is defined as 'Last Patient Last Visit (LPLV)' for the clinical trial. For clinical trials where subjects are followed up remotely after LPLV (e.g. survival follow-up via telephone calls or safety follow-up etc.), **study completion is defined as the end of remote follow-up**.

Ref: Guidance on Regulatory Requirements for New Applications and Subsequent Submissions

TRIAL STATUS REPORT

Trial Site Status Report				
List of Principal Investigator(s) & Clinical Trial Site(s)				
☑	Principal Investigator	Clinical Trial Site	Date of Approval	Trial Site Status
☑	A	KK WOMEN'S AND CHILDREN'S HOSPITAL	23/03/2016	
☑	A	National University Hospital	23/03/2016	

Retrieve Saved Draft Report(s) Retrieve Last Submitted Report(s)

- **A maximum of 2 trial sites can be retrieved at one time.**
- **Please click on "Retrieve Saved Draft Report(s)" button to retrieve status report details if:**
  a) no status report has been submitted previously for the trial site, or
  b) there is a saved status report in the current application.
- **Please click on "Retrieve Last Submitted Report(s)" button to retrieve status report details if a status report has been submitted previously to HSA.**
- **Trial site(s) with "Completed", "Terminated" or "Premature Site Closure" status are not allowed to be updated. To view, please click on "Retrieve Saved Draft Report(s)".**

TRIAL STATUS REPORT

Status Report	Centre 1	Centre 2
Name of Principle Investigator	A	A
Designation	Consultant	Consultant
Name of Trial Site	KK WOMEN'S AND CHILDREN'S HOSPITAL	National University Hospital
Planned No. of Clinical Trial Subjects	10	10
3.8 Trial Site Status *^	Select One	Select One Not Yet Recruiting Ongoing, Recruiting Ongoing, Recruitment Suspended Ongoing, Recruitment Closed Premature Closure Suspended Terminated Completed
3.9 Date of Trial Site Initiation		
3.10 If clinical trial has not started recruitment, please provide reason		
3.11 Date of Trial Site Suspension	Please provide reason:	
3.12 Date of Trial Site Termination	Please provide reason:	Please provide reason:
3.13 Date of Trial Site Closure	Please provide reason:	Please provide reason:

TRIAL STATUS REPORT

Recruitment Status		
Are there any changes to 3.14 to 3.17 since the last status report?	○ No ◉ Yes	○ No ◉ Yes
3.14 No. of subjects screened	0	0
3.15 No. of screened failures	0	0
3.16 No. of subjects pending screening outcome	0	0
3.17 No. of subjects enrolled (i.e. Randomised) (Numbers in 3.15 to 3.17 should add up to 3.14)	0	0
Subjects enrolled		
Are there any changes to 3.18 to 3.20 since the last status report?	○ No ◉ Yes	○ No ◉ Yes
3.18 No. of subjects withdrawn or prematurely terminated	0 Please provide reasons:	0 Please provide reasons:
3.19 No. of subjects ongoing	0	0
3.20 No. of subjects completed (Numbers in 3.18 to 3.20 should add up to 3.17)	0	0
3.21 No. of SAEs experienced by local subjects	0	0
3.22 Has there been an internal audit conducted for this clinical trial site?	◉ Yes ○ No	◉ Yes ○ No

Save

Ref: Guidance on Regulatory Requirements for New Applications and Subsequent Submissions

Previous Next Reset

HSA Health Sciences Authority

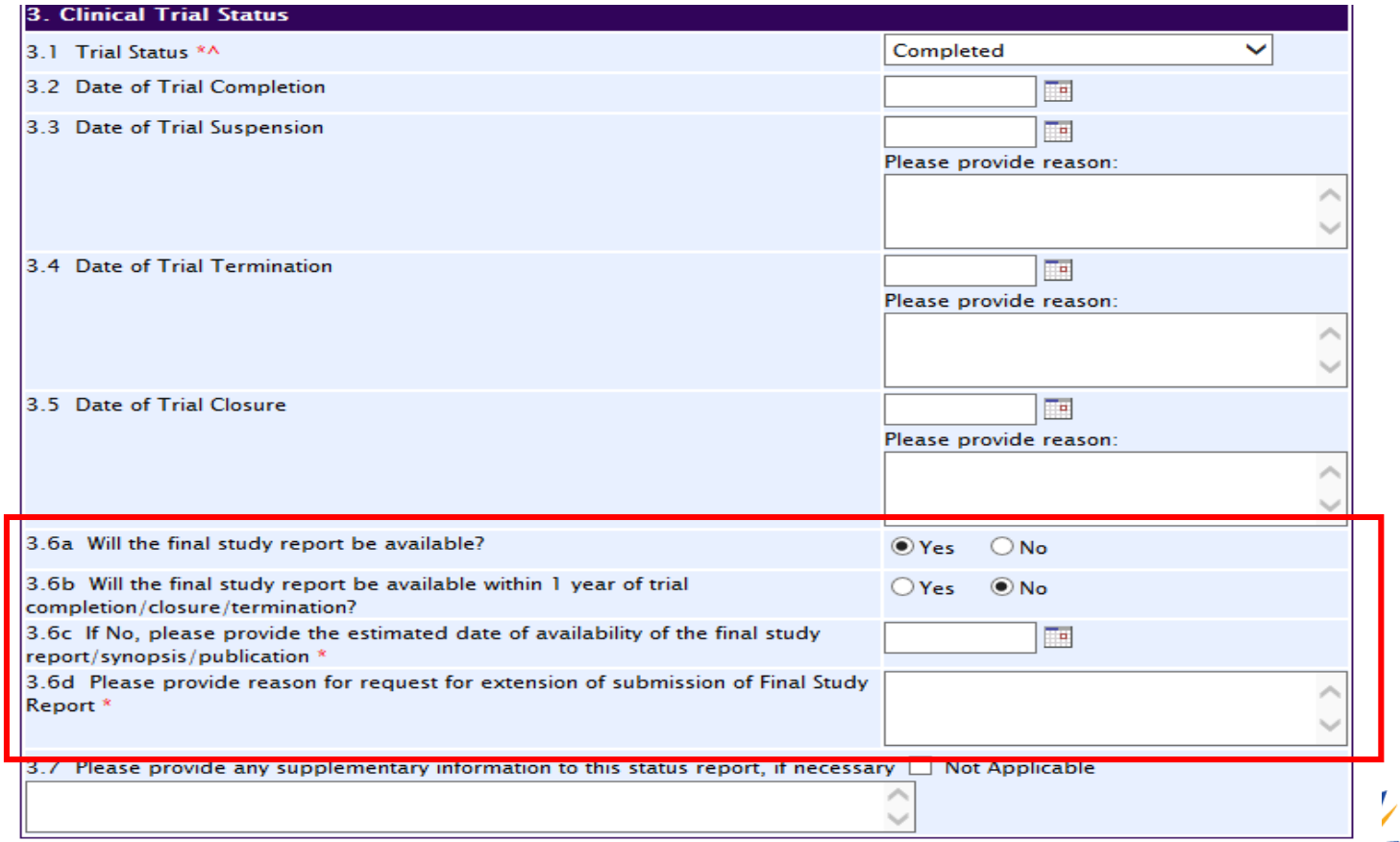
FINAL TRIAL REPORT

TRIAL COMPLETION

- Upon trial completion,
  - Sponsor to notify HSA (via *trial status report*) within 30 days of trial conclusion.
  - In addition, sponsor to submit final report of trial within 1 year after date of trial conclusion, or such longer period as the Authority may allow in any particular case.

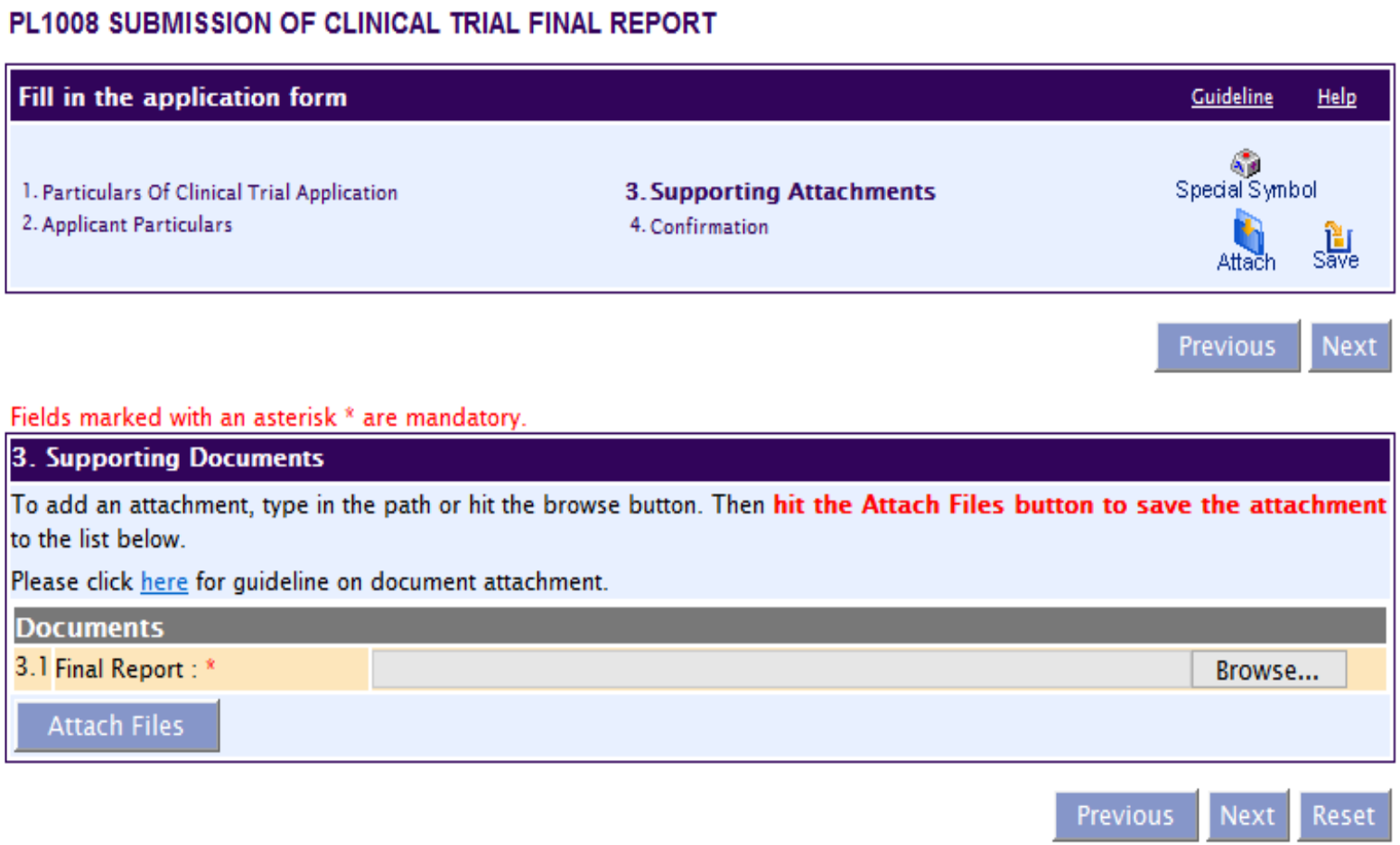
TRIAL COMPLETION

During the submission of trial status report, the following will be displayed if the trial status is “Premature closure”, “Terminated” or **“Completed”** :



Section appears if trial status is “Premature closure”, “Terminated” or “Completed”.

FINAL TRIAL REPORT



OUTLINE

Other PRISM Submissions

- Serious breaches
- Urgent safety measures
- Trial status report
- Final study report

PRISM Functions

- Track @ PRISM
- Enquire @ PRISM

PRISM FUNCTIONS

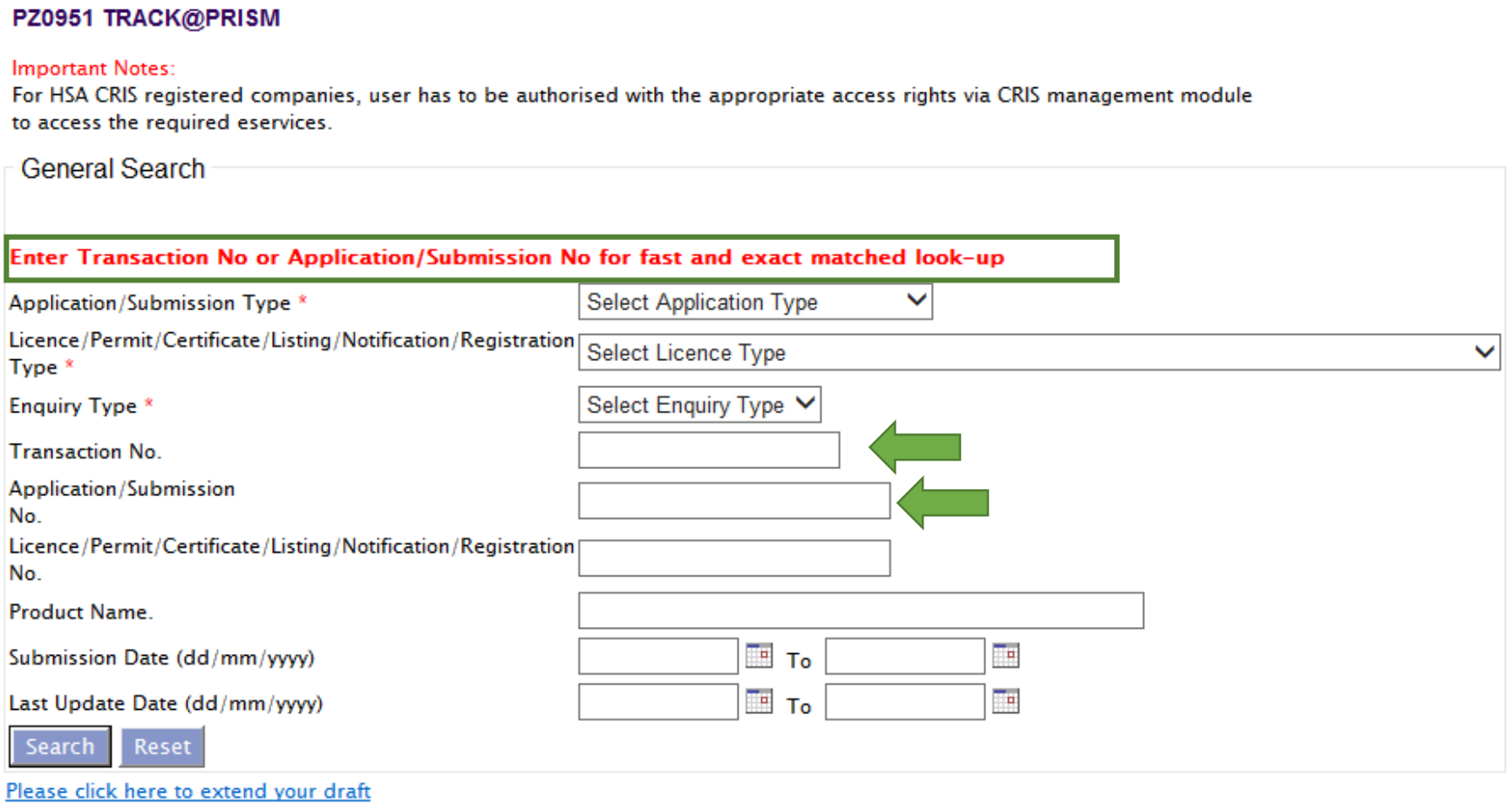
Track @ PRISM

- Search your **application**
  - Check status of your application
  - Check endorsement by various parties for your draft application

Enquire @ PRISM

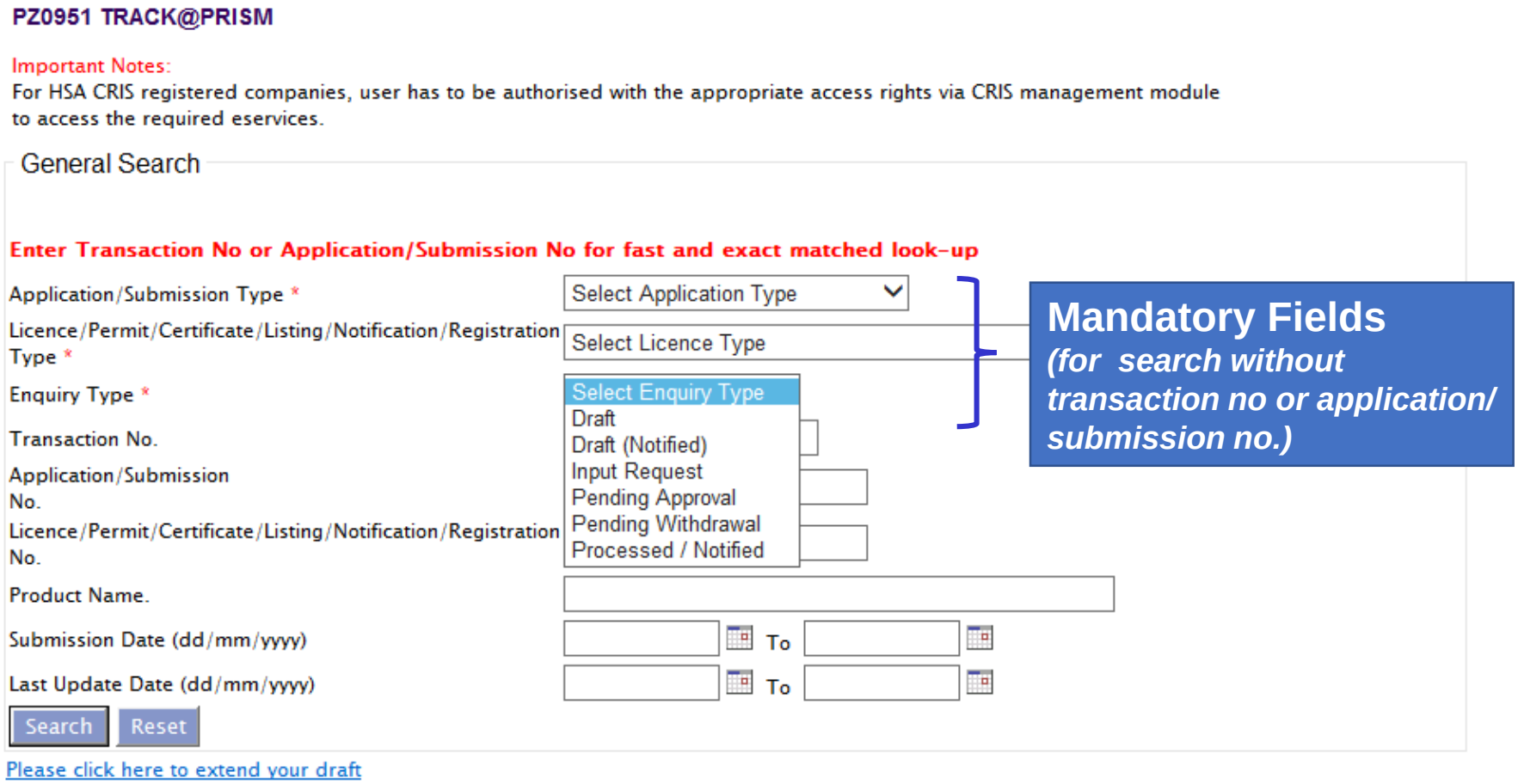
- Search your **licence** (i.e. CTA/ CTN/ CTC)
- Search your **CRM Notification**

TRACK @ PRISM



TRACK @ PRISM

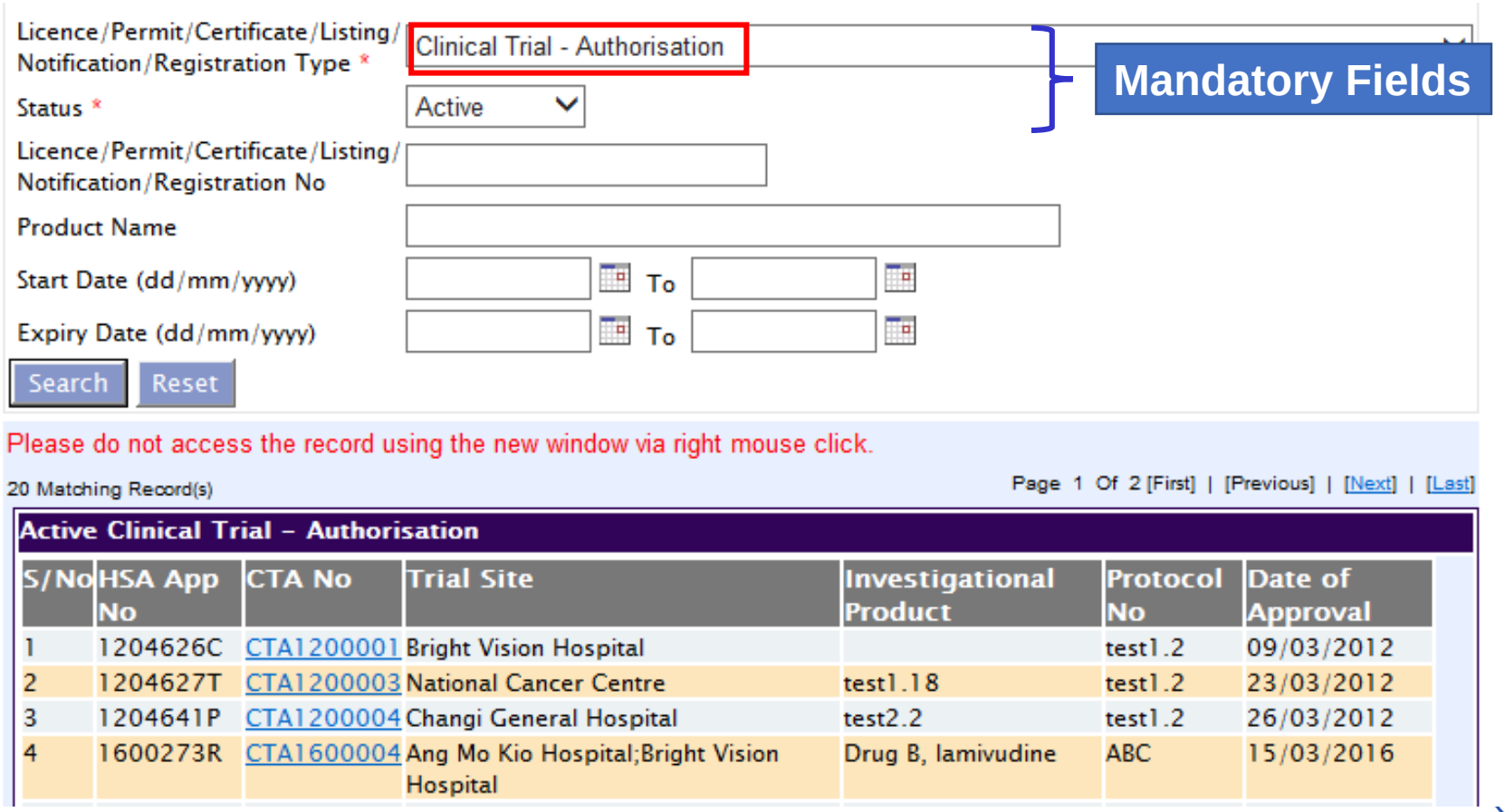
- Search your <u>new</u> application – enter “New Application/ Submission”
- Search amendment application - enter “Amendment”



ENQUIRE @ PRISM

ENQUIRE @ PRISM

- Search your licence (i.e. CTA/ CTN/ CTC)



ENQUIRE @ PRISM

CTA (Sample)

PZO901 ENQUIRE@PRISM

1. Licence/Permit/Certificate/Listing/Notification Summary	
1.1 Licence/Permit/Certificate/Listing/ Notification Type:	Clinical Trial Authorisation
1.2 Licence/Permit/Certificate/Listing/ Notification No:	CTA1600016
1.3 Company Name:	ABC Co Ltd.,
1.4 Approval/Acceptance Date:	23/03/2016

Authorisation Date

2. Particulars of Clinical Trial	
2.1 PRISM CTA/CTN Application No:	1600420W
2.2 Title of Clinical Trial:	This is a CTA
2.3 Protocol Number:	123
2.4 Investigational Product(s):	CTA1 CTA2
2.5 Local Sponsor(s):	ABC Co Ltd.

Trial Information

3. List of Principal Investigator(s) & Clinical Trial Site(s)	
Principal Investigator	**Clinical Trial Site**
abc	HMI Balestier Hospital

Site/ PI Information

4. The Clinical Trial Authorisation has been granted for the conduct of the clinical trial, subject to the provisions of the Health Products Act and its subsidiary legislation, and also to the following conditions:
NA.

Licensing Conditions (if any)

The above information is current as of the date of print: 11/10/2016

ENQUIRE @ PRISM

CTN (Sample)

PZO901 ENQUIRE@PRISM

1. Licence/Permit/Certificate/Listing/Notification Summary	
1.1 Licence/Permit/Certificate/Listing/ Notification Type:	Clinical Trial Notification
1.2 Licence/Permit/Certificate/Listing/ Notification No:	CTN1600037
1.3 Company Name:	LION VIEW MINIMART
1.4 Approval/Acceptance Date:	05/10/2016

Acceptance Date

2. Particulars of Clinical Trial	
2.1 PRISM CTA/CTN Application No:	1601118E
2.2 Title of Clinical Trial:	ABCDE for NSCLC
2.3 Protocol Number:	ABCDENSCLC
2.4 Investigational Product(s):	ABCDE
2.5 Local Sponsor(s):	LION VIEW MINIMART

Trial Information

3. List of Principal Investigator(s) & Clinical Trial Site(s)	
Principal Investigator	**Clinical Trial Site**
Principal Investigator	National Cancer Centre

Site/ PI Information

4. The Clinical Trial Notification has been granted for the conduct of the clinical trial, subject to the provisions of the Health Products Act and its subsidiary legislation, and also to the following conditions:
NA.

Licensing Conditions (if any)

The above information is current as of the date of print: 11/10/2016

ENQUIRE @ PRISM

CTC (Sample)

PZO901 ENQUIRE@PRISM

1. Licence/Permit/Certificate/Listing/Notification Summary	
1.1 Licence/Permit/Certificate/Listing/ Notification Type:	Clinical Trial Certificate
1.2 Licence/Permit/Certificate/Listing/ Notification No:	CTC1600036
1.3 Company Name:	ABC Co Ltd.,
1.4 Approved Date:	05/10/2016

Approved Date

2. Particulars of Clinical Trial	
2.1 PRISM CTC Application No:	1601153J
2.2 Title of Clinical Trial:	This is a CTC application
2.3 Protocol Number:	0987
2.4 Investigational Product(s):	CTC Drug 1
2.5 Local Sponsor(s):	ABC Co Ltd.

Trial Information

3. List of Principal Investigator(s) & Clinical Trial Site(s)			
Principal Investigator	**Clinical Trial Site**	**CTC No.**	**Date of Approval**
PI	Kwong Wai Shiu Hospital	CTC1600036	05/10/2016

The certificate is granted under the Medicines (Clinical Trials) Regulations, to the abovementioned PI(s) as pe
1601153J relating to the use of :

CTC Drug 1

Site/ PI Information

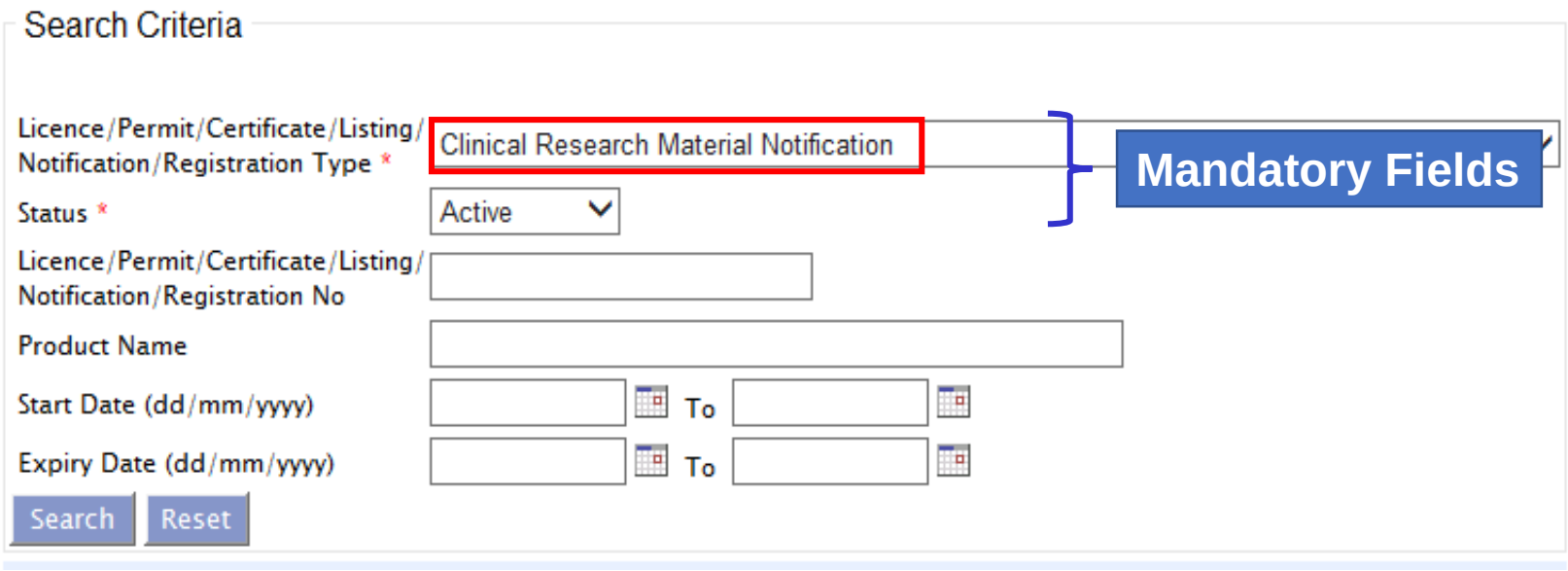
4. The CTC is issued subject to the provisions of the Medicines Act, and to any regulations and orders made thereafter and, also to the following conditions:
NA.

Licensing Conditions (if any)

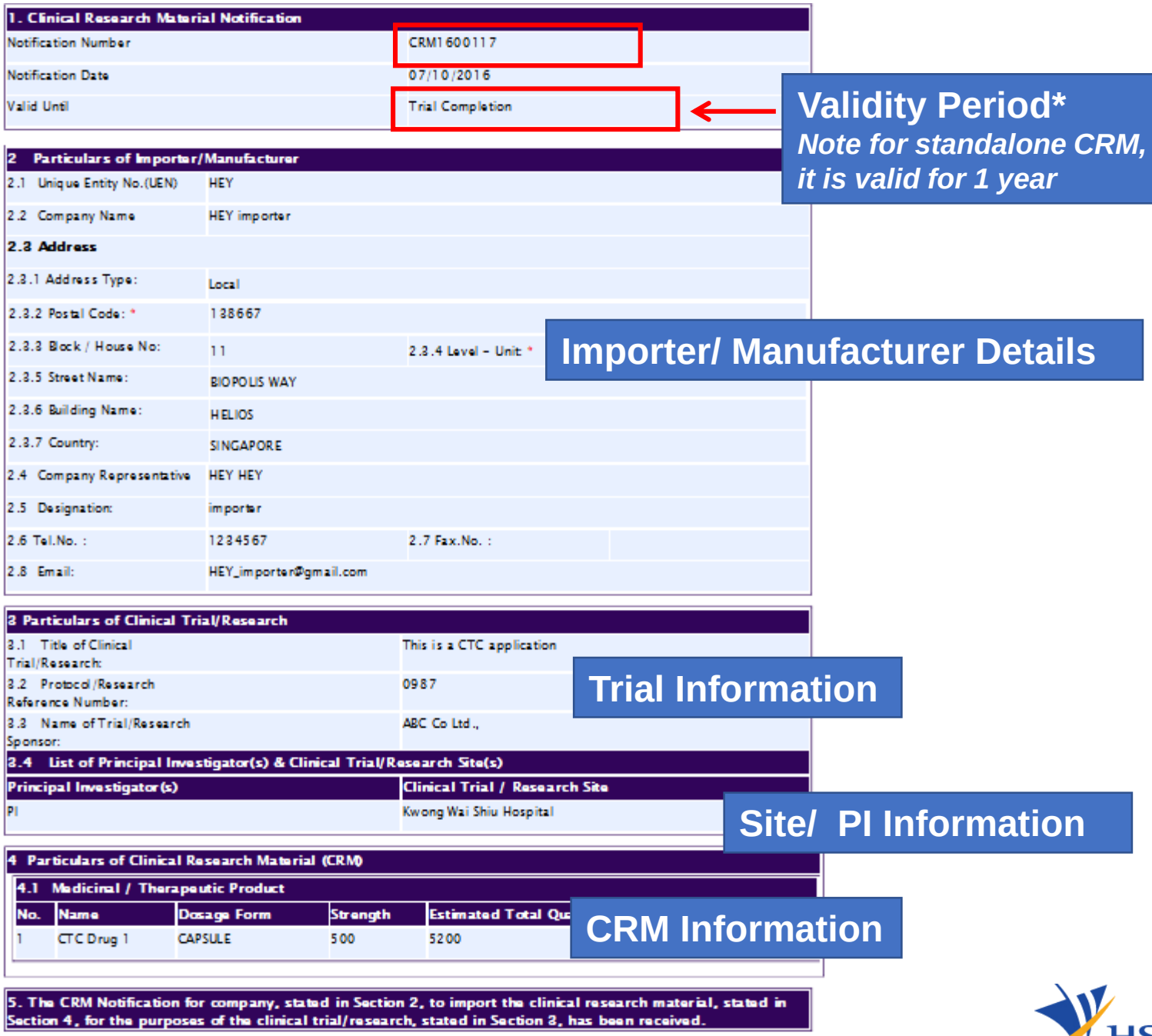
The above information is current as of the date of print: 11/10/2016

ENQUIRE @ PRISM

- Search your CRM Notification



CRM Notification (Sample)



1. Clinical Research Material Notification

Notification Number	CRM1600117
Notification Date	07/10/2016
Valid Until	Trial Completion

Validity Period*
Note for standalone CRM, it is valid for 1 year

2 Particulars of Importer/Manufacturer

2.1 Unique Entity No.(UEN)	HEY		
2.2 Company Name	HEY importer		
2.3 Address			
2.3.1 Address Type:	Local		
2.3.2 Postal Code: *	138667		
2.3.3 Block / House No:	11	2.3.4 Level - Unit: *	
2.3.5 Street Name:	BIOPOLIS WAY		
2.3.6 Building Name:	HELIOS		
2.3.7 Country:	SINGAPORE		
2.4 Company Representative	HEY HEY		
2.5 Designation:	importer		
2.6 Tel.No. :	1234567	2.7 Fax.No. :	
2.8 Email:	HEY_importer@gmail.com		

Importer/ Manufacturer Details

3 Particulars of Clinical Trial/Research

3.1 Title of Clinical Trial/Research:	This is a CTC application
3.2 Protocol/Research Reference Number:	0987
3.3 Name of Trial/Research Sponsor:	ABC Co Ltd.,

Trial Information

3.4 List of Principal Investigator(s) & Clinical Trial/Research Site(s)

Principal Investigator(s)	Clinical Trial / Research Site
PI	Kwong Wai Shiu Hospital

Site/ PI Information

4 Particulars of Clinical Research Material (CRM)

4.1 Medicinal / Therapeutic Product

No.	Name	Dosage Form	Strength	Estimated Total Qu
1	CTC Drug 1	CAPSULE	500	5200

CRM Information

5. The CRM Notification for company, stated in Section 2, to import the clinical research material, stated in Section 4, for the purposes of the clinical trial/research, stated in Section 3, has been received.

We welcome your queries!

HSA_CT@hsa.gov.sg

THANK YOU!