

TRAINING SESSION:

ENHANCED PRISM E-SERVICES

OTHER CLINICAL TRIALS SUBMISSIONS TRACK & ENQUIRE @ PRISM



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OUTLINE

Other PRISM Submissions

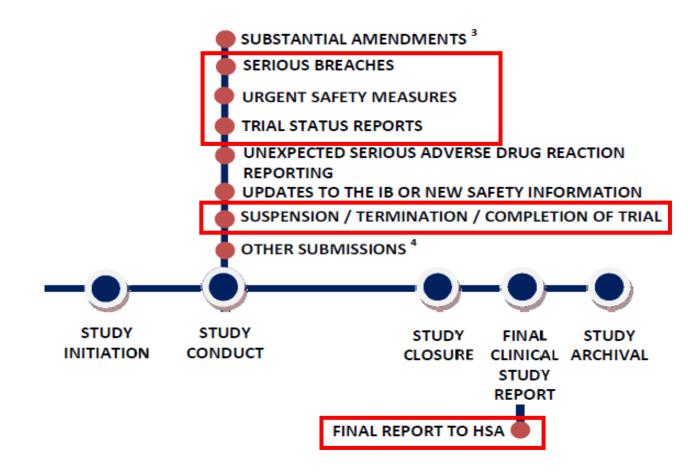
- Serious breaches
- Urgent safety measures
- Trial status report
- Final study report

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.



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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



5

SERIOUS BREACHES

SERIOUS BREACHES FORM

Protocol No.:				1	1	
Protocol No: HSA Ref: USA Ref: USA Ref: USA Ref: USA Ref: USA Ref: Date of awareness of Serious Breach Date Serious Breach Notified to HSA: Date of awareness of Serious Breach Date Serious Breach Date of awareness of Serious Breach Date of awareness of Serious Breach Date of awareness of Serious Breach Date of awareness of Serious Breach Date of wareness of Breach Date of user of Serious Breach Details of Serious Breach	Protocol Title:					
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Organization:	HSA Ref:					
Contact Details:	Name:					
Date of awareness of Serious Breach:	Organization:					
Serious Breach: Image: Construction of the serious breach indicated on the serious breach indicated if the non-compliance was a serious breach in the scientific value of the trial From 1st Nov 2016 onwards,	Contact Details:					
Date Serious Breach Notified to HSA: [rick appropriately] Initial Report Follow-up Report DETAILS OF SERIOUS BREACH Category of serious breach Adverse event reporting Informed consent Support Serious Breach Support Seri	Date of awareness of					
Date Serious Breach Notified to HSA: [rick appropriately] Initial Report Follow-up Report DETAILS OF SERIOUS BREACH Category of serious breach Adverse event reporting Informed consent Support Serious Breach Support Seri	Serious Breach:					From 1 st Nov
Report: (Tick appropriately) Initial Report Follow-up Report DETAILS OF SERIOUS BREACH Category of serious breach Adverse event reporting Informed consent Adverse event reporting Informed consent Subjects in the follow-up Report Please indicate if the non- compliance was a serious breach to the following Baudwinstaion and blinding Subjects in the clinical trial Practice (SGGCP) Elaborate on corrective and preventive actions implemented / to be implemented as a result of this serious breach Elaborate on corrective and preventive actions PRISIM	Date Serious Breach					
Interspectively DETAILS OF SERIOUS BREACH Calegory of serious breach Adverse event reporting Adverse event reporting Investigational product Adverse event reporting Investigational product Bandomisation and blinding Source documentation Study conduct Use of unapproved documents Pequilations Please indicate if the non- compliance was a serious breach to the following Protocol Protocol Singapore Guideline for Good Clinical Practice (SGGCP) Significant Impact of Serious Breach to: The salety or physical or mental integrity of subjects in the clinical trial Details of Serious Breach Please do not provide any The solentific value of the trial	Notified to HSA:					
Interspectively DETAILS OF SERIOUS BREACH Calegory of serious breach Adverse event reporting Adverse event reporting Investigational product Adverse event reporting Investigational product Bandomisation and blinding Source documentation Study conduct Use of unapproved documents Pequilations Please indicate if the non- compliance was a serious breach to the following Protocol Protocol Singapore Guideline for Good Clinical Practice (SGGCP) Significant Impact of Serious Breach to: The salety or physical or mental integrity of subjects in the clinical trial Details of Serious Breach Please do not provide any The solentific value of the trial	Report:	Initial Report Follow-up Report				2016 onwards
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Significant impact of Serious Breach to: subjects in the clinical trial the scientific value of the trial the scientific value of the trial this serious breach Please do not provide any	references:	Practice (SGGCP)	preventive actions			
Please do not provide any	Significant Impact of Se Breach to:	subjects in the clinical trial	implemented as a result of			
Please do not provide any	Details of Serious Bread					
	Please do not provide any	y				



SERIOUS BREACHES

	Fill in the application form	<u>Guideline Help</u>
	1. Particulars Of Clinical Trial Application 3. Clinical Trial Serious Breach Report 2. Applicant Particulars 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 *	< >
yright © HSA, All rigł	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



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 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.



ill in the application form			<u>Guideline Help</u>
Particulars Of Clinical Trial Application Applicant Particulars	3. Clinical Trial Status 4. Supporting Attachments	5. Confirmation	Special Symbol Attach Save
lds marked with an asterisk * are mandat			Previous
Ids marked with ^ will be displayed in the Clinical Trial Status	Clinical Trial Register.		
1 Trial Status *^		select One	
2 Date of Trial Completion		Not Yet Recruiting Ongoing, Recruiting	
3 Date of Trial Suspension		Ongoing, Recruitme Ongoing, Recruitme Premature Closure Suspended Terminated Completed	ent Suspended
4 Date of Trial Termination		Please provi de rear	
5 Date of Trial Closure			
		Please provide reas	on:
7 Please provide any supplementary infor	mation to this status report, if nece	ssary 🗹 Not Applicable	2
		<u>^</u>	

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 <u>no subjects were</u> <u>screened</u> 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.

copyRef:@Guidange.ons&Regulatory Requirements for New Applications and Subsequent Submissions

HSA

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)".



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 🗸	Silect One	
3.9 Date of Trial Site Initiation		Not Yet Recruiting Ongoing, Recruiting	
3.10 If clinical trial has not started recruitment, please provide reason	~	Ongoing, Recruitment Suspended Ongoing, Recruitment Closed Premature Closure Suspended	
3.11 Date of Trial Site Suspension	Please provide reason:	Terminated Completed	
	~	<u> </u>	
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:	
	^	^	
	~	~	

HSA

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Are there any changes to 3.14 to 3.17 since the last status report?	○ No ●Yes	○No	
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	
3.18 No. of subjects withdrawn or prematurely terminated	0 Please provide reasons:	0 Please provide reasons:	
		\sim	
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 O No	●Yes ○No	

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



FINAL TRIAL REPORT



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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" :

3. Clinical Trial Status		
3.1 Trial Status *^	Completed	~
3.2 Date of Trial Completion		
3.3 Date of Trial Suspension		
	Please provide reason:	
		~
		~
3.4 Date of Trial Termination		
	Please provide reason:	
		~
		\sim
3.5 Date of Trial Closure		
	Please provide reason:	
		~
3.6a Will the final study report be available?	●Yes ○No	
3.6b Will the final study report be available within 1 year of trial completion/closure/termination?	⊖Yes ●No	
3.6c If No, please provide the estimated date of availability of the final study report/synopsis/publication *		
3.6d Please provide reason for request for extension of submission of Final Study		~
Report *		\sim
3.7 Please provide any supplementary information to this status report it peressai	Not Applicable	
	V	
L		
	 3.1 Trial Status *^ 3.2 Date of Trial Completion 3.3 Date of Trial Suspension 3.4 Date of Trial Termination 3.5 Date of Trial Closure 3.6a Will the final study report be available? 3.6b Will the final study report be available within 1 year of trial completion/closure/termination? 3.6c If No, please provide the estimated date of availability of the final study report sport for extension of submission of Final Study Report * 	3.1 Trial Status *^ Completed 3.2 Date of Trial Completion Image: Completed 3.3 Date of Trial Suspension Image: Completed 3.4 Date of Trial Termination Image: Completed 3.4 Date of Trial Termination Image: Completed 3.5 Date of Trial Closure Image: Completed 3.6a Will the final study report be available? Image: Completed 3.6b Will the final study report be available within 1 year of trial completion/closure/termination? Image: Completed Study 3.6c If No, please provide the estimated date of availability of the final study report/synopsis/publication * Image: Completion of Study 3.6d Please provide reason for request for extension of submission of Final Study Image: Completion Study

FINAL TRIAL REPORT

PL1008 SUBMISSION OF CLINICAL TRIAL FINAL REPORT

Fill in the application form		<u>Guideline</u> <u>Hel</u> r
1. Particulars Of Clinical Trial Application 2. Applicant Particulars	3. Supporting Attachments 4. Confirmation	Special Symbol Attach Save
		Previous Ne

Fields marked with an asterisk * are mandatory.

To add an attachment, type in the nath or hit the browse button. Then hit the Attach Files, button to save the at				
To add an attachment, type in the path or hit the browse button. Then <mark>hit the Attach Files button to save the attachment</mark> to the list below.				
Please click here for guideline on document attachment.				
Documents				
3.1 Final Report : * Brow	se			
Attach Files				



Reset

Previous

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 <u>application</u>
 - Check status of your application
 - Check endorsement by various parties for your <u>draft</u> application

Enquire @ PRISM

- Search your <u>licence</u> (i.e. CTA/ CTN/ CTC)
- Search your <u>CRM Notification</u>



TRACK @ PRISM

PZ0951 TRACK@PRISM

Important Notes:

For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

General Search		
Enter Transaction No or Application/Submission N	o for fast and exact matched look-up	
Application/Submission Type *	Select Application Type	
Licence/Permit/Certificate/Listing/Notification/Registration Type *	Select Licence Type	~
Enquiry Type *	Select Enquiry Type V	
Transaction No.		
Application/Submission No.		
Licence/Permit/Certificate/Listing/Notification/Registration No.		
Product Name.		
Submission Date (dd/mm/yyyy)	То 🔲	
Last Update Date (dd/mm/yyyy)	То П	
Search Reset		
Please click here to extend your draft		



TRACK @ PRISM

- Search your <u>new</u> application enter "New Application/ Submission"
- Search amendment application enter "Amendment"

PZ0951 TRACK@PRISM

Important Notes:

For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

General Search	
Enter Transaction No or Application/Submission N	o for fast and exact matched look-up
Application/Submission Type *	Select Application Type
Licence/Permit/Certificate/Listing/Notification/Registration Type *	Select Licence Type Mandatory Fields (for search without
Enquiry Type *	Select Enquiry Type transaction no or application/
Transaction No.	Draft Joraft (Notified)
Application/Submission No.	Input Request Pending Approval
Licence/Permit/Certificate/Listing/Notification/Registration No.	Pending Withdrawal Processed / Notified
Product Name.	
Submission Date (dd/mm/yyyy)	
Last Update Date (dd/mm/yyyy)	То
Search Reset	
Please click here to extend your draft	



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

Licence/Permit/Certificate/Listing/ Notification/Registration Type *	Clinical Trial - Authorisati	ion	Ţ	Mandatory Fields
Status *	Active V			manualory ricius
Licence/Permit/Certificate/Listing/ Notification/Registration No				
Product Name				
Start Date (dd/mm/yyyy)	То			
Expiry Date (dd/mm/yyyy)	То			
Search Reset				

Please do not access the record using the new window via right mouse click.

20 Matching Record(s)

Page 1 Of 2 [First] | [Previous] | [Next] | [Last]

Active Clinical Trial - Authorisation						
S/No	HSA App No	CTA No	Trial Site	Investigational Product	Protocol No	Date of Approval
1	1204626C	CTA1200001	Bright Vision Hospital		test1.2	09/03/2012
2	1204627T	CTA1200003	National Cancer Centre	test1.18	test1.2	23/03/2012
3	1204641P	CTA1200004	Changi General Hospital	test2.2	test1.2	26/03/2012
4	1600273R		Ang Mo Kio Hospital;Bright Vision Hospital	Drug B, Iamivudine	ABC	15/03/2016



CTA (Sample)

PZO901 ENQUIRE@PRISM

1. Licence/Permit/Certificate/Listin	g/Notification Summary	1		
1.1 Licence/Permit/Certificate/Listing/ Notification Type:	Clinical Trial Authorisatio	on		
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 Da	ite
2. Particulars of Clinical Trial				1
2.1 PRISM CTA/CTN Application No:	1600420W		Trial Infor	motion
2.2 Title of Clinical Trial:	This is a CTA		Trial mor	mation
2.3 Protocol Number:	123			
2.4 Investigational Product(s):	CTA1 CTA2			
2.5 Local Sponsor(s):	ABC Co Ltd.			
3. List of Principal Investigator(s) &	Clinical Trial Site(s)			
Principal Investigator	Cli	nical Trial Site	Site/ PI Inf	ormation
abc	HM	II Balestier Hospital	Site/ I I III	ormation
4. The Clinical Trial Authorisation provisions of the Health Products A				
NA.		Li	censing Condition	s (if any)

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

HSA

CTN (Sample)

PZO901 ENQUIRE@PRISM

1.1 Licence/Permit/Certificate/Listing/ Notification Type:		Clinical Trial N	otification	
1.2 Licence/Permit/Certificate/Listing/ Notification No:		CTN1600037		
1.3 Company Name:		LION VIEW MIN	IMART	
1.4 Approval/Acceptance Date:		05/10/2016	Acce	otance Dat
2. Particulars of Clinical Trial				
2.1 PRISM CTA/CTN Application No:	1601118E		Trial Informa	tion
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			
3. List of Principal Investigator(s)	& Clinical Trial Site(s)			
Principal Investigator		Clinical Trial Site		
		National Cancer Centre	Site/ PI In	tormation

CTC (Sample)

PZO901 ENQUIRE@PRISM

 Licence/Permit/Certificate/Listing/ Notification Type: Licence/Permit/Certificate/Listing/ Notification No: Company Name: 			Clinical Trial Certific	ate			
1.2 Licence/Permit/Certificate/Listing/ Notification No:			CTC1600036				
1.3 Company Name:			CTC1600036				
			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 ap	plication	Tri	al Infe	orm	atio	on
2.3 Protocol Number:	0987						
2.4 Investigational Product(s):	CTC Drug 1						
2.5 Local Sponsor(s):	ABC Co Ltd.						
3. List of Principal Investigator(s)	& Clinical Trial Sit	e(s)]
Principal Investigator Clinic	al Trial Site	CTC No.	Date o	of Approva	ıl		
PI Kwong	Wai Shiu Hospital	CTC1600036	05/10/	²⁰¹⁶ S	te/	ΡΙ	Information
The certificate is granted under the Me 1601153 relating to the use of :	dicines (Clinical Trials) Regulations, to the	e abovementioned PI(s) a				
CTC Drug 1							
]
The CTC is issued subject to the thereafter and, also to the followi		e Medicines Act,	and to any regulatio	ns and or	ders n	nade	
NA.			Licen	sing	Cor	dit	ions (if any)
he above information is current as of th				Sing	501		

HSA

Search your CRM Notification

Search Criteria	
Licence/Permit/Certificate/Listing/ Notification/Registration Type *	Clinical Research Material Notification - Mandatory Fields
Status *	Active V
Licence/Permit/Certificate/Listing/ Notification/Registration No	
Product Name	
Start Date (dd/mm/yyyy)	То
Expiry Date (dd/mm/yyyy)	То
Search Reset	





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CRM



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THANK YOU!

We welcome your queries!