Clinical Trials Authorization (CTA)

1 to 5 December 2014

Jakarta, Indonesia

APPLICATION FORM

IMPORTANT: All sections of this application MUST be filled in for the application to be considered valid. The application form is designed in a FORM format to allow participants to fill it electronically. The cells may expand as you enter more information

All application forms should be accompanied by a Curriculum Vitae (CV). Submit your application form and CV directly to the GLO/VQ Secretariat at the World Health Organization in Geneva, Switzerland:

Dr Ümit Kartoğlu, GLO/VQ Coordinator, kartogluu@who.int

Ms Sinéad Jones, GLO/VQ Assistant, jonessi@who.int

Fax: +41 22 791 4384

World Health Organization
RSS/EMP/RHT
20 Avenue Appia, CH-1211 Geneva 27, Switzerland

PART 1: Personal information of applicant *Important! For applicants with several names, please make sure you indicate CLEARLY your Family, First and Middle names in the correct boxes below*	
Family name:	**First name:**
Middle name:	
Please indicate how you would like your name to appear on your certificate (once course is completed):	
Title: *(please mark one)* ☐ Mr ☐ Mrs ☐ Ms ☐ Dr	**Gender:** *(please mark one)* ☐ *Male* ☐ Female
Nationality:	**Date of birth (dd/mm/yyyy):**
Details of passport: **(a) Number:** **(b) Issuing authority:** **(c) Date of issue:** **(d) Date of expiry:** **(e) Your full name as indicated on your passport:**	

PART 2: Institution/organization details		
Name of your institution/organization		
Full professional mailing address including city/country (not just P.O. Boxes)		
Contact details (including international and area codes)	**Tel:** **Fax:**	**Mobile phone:** **E-mail:**
Job title and description		

Briefly describe how your job relates to this course	

WHO SHOULD APPLY

NRAs sending representatives to "CTA" course must document that there are clinical trials conducted in the country, that the NRA has or is in the process to implement the legal/regulatory framework to authorize clinical trials.

Representatives from the national regulatory authorities (NRA): The person is responsible or designated to be responsible after completion of this course, for the review of clinical trial applications. They may be pharmacists, biochemists, doctors, or hold another health-related degree.

PART 3: Funding information – <u>please</u> fill this part out!		
Is funding (full or partial) available from the applicant's Institute?	☐ Yes	☐ No
If yes, please indicate amount available:		
Is funding (full or partial) available from your WHO Country Office?	☐ Yes	☐ No
If yes, please indicate amount available:		
Is funding (full or partial) available from your WHO Regional Office?	☐ Yes	☐ No
If yes, please indicate amount available:		

PART 4: Endorsement			
	Type or print name legibly	**Signature**	**Date**
Applicant			
Clearance (approval and/or senior management)			
WHO Regional Office approval			

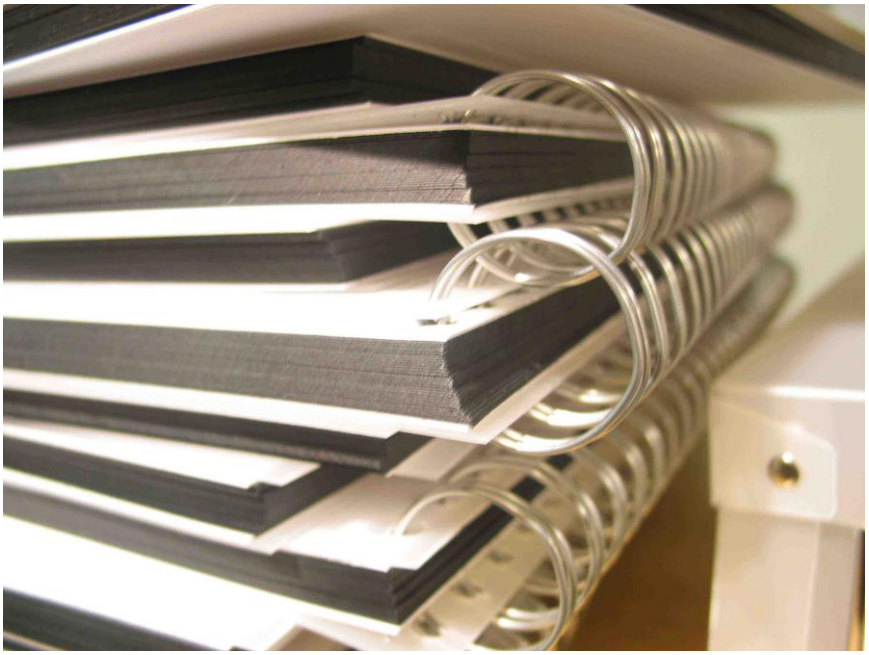
Required attachments:

Curriculum vitae

IMPORTANT ! ***Your application form will not be accepted without your CV***

Evaluation of Clinical Data

3 to 7 November 2014
Jakarta, Indonesia
APPLICATION FORM



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Middle name:	
Please indicate how you would like your name to appear on your certificate (once course is completed):	
Title: *(please mark one)* ☐ Mr ☐ Mrs ☐ Ms ☐ Dr	**Gender:** *(please mark one)* ☐ *Male* ☐ Female
Nationality:	**Date of birth (dd/mm/yyyy):**
Details of passport: **(a) Number:** **(b) Issuing authority:** **(c) Date of issue:** **(d) Date of expiry:** **(e) Your full name as indicated on your passport:**	

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Full professional mailing address including city/country (not just P.O. Boxes)		
Contact details (including international and area codes)	**Tel:** **Fax:**	**Mobile phone:** **E-mail:**
Job title and description		

Briefly describe how your job relates to this course	

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Is funding (full or partial) available from your WHO Regional Office?	☐ Yes	☐ No
If yes, please indicate amount available:		

PART 4: Endorsement

	Type or print name legibly	**Signature**	**Date**
Applicant			
Clearance (approval and/or senior management)			
WHO Regional Office approval			

Required attachments:

Curriculum vitae

IMPORTANT ! Y*our application form will not be accepted without your CV*

WHO SHOULD APPLY

Representatives from the national regulatory authorities (NRA): Inspectors responsible for clinical data evaluation. Countries sending participants to the course should document that there are clinical trials conducted in the country, that the NRA has or is in the process to implement the legal/regulatory framework.

World Health Organization

GLO/VQ Global Learning Opportunities for Vaccine Quality

2014

Learning opportunities

Course	Dates	Language	Max number of participants	Application deadline	Comments
e-VVM-based Vaccine Management (NEW)	27 Jan-28 Mar (beta-course) 21 Apr-20 Jun 6 Oct-5 Dec	English	15	n/a	The course takes 9 weeks to complete. For course details please go to: http://epela.net/epela_web/evvm.html . For applying online, please go to: http://epela.net/epela_web/apply_online_evvm.html
e-Pharmaceutical Cold Chain Management	3 Feb-25 Apr 5 May-25 Jul 8 Sept-28 Nov	English	15	n/a	The course takes 11 weeks to complete. For course details please go to: http://epela.net/epela_web/introduction.html. For applying online, please go to: http://epela.net/epela_web/apply_online.html
Product Evaluation Tunis, Tunisia	18-23 May	English	15	COMPLETED	For officers from NRAs with a level of proficiency that is sufficient for the review of a CTD dossier. Organized by WHO Eastern Mediterranean office.
GCP Inspection Jakarta, Indonesia	9-13 Jun	English	14	COMPLETED	NRAs sending representatives to "GCP inspection" course must document that the NRA has the legal/regulatory framework in place to authorize clinical trials and to perform inspections once the trial is started.
Pharmaceutical Cold Chain Management on Wheels In association with Tip Kurumu, Turkey	9-14 Jun	English	15	COMPLETED	NRA representatives of vaccine producing countries, supply, packaging and distribution unit, representatives from WHO prequalified vaccine manufacturers, representatives from PQS prequalified manufacturers and pharmaceutical industry
Evaluation of Clinical Data Amman, Jordan	7-11 Sept	English	14	15 Jul	For NRA representatives responsible for evaluation of clinical data. Organized by WHO Eastern Mediterranean office.
Advanced GMP Osong, Republic of Korea	16-24 Sept	English	14	30 July	Target audience is staff from inspectorate in NRAs. They should have not less than 3 years' experience in GMP inspections.
Facilitation Skills Antalya, Turkey	20-24 Oct	English	15	15 Aug	By invitation only
Evaluation of Clinical Data Jakarta, Indonesia	3-7 Nov	English	14	15 Sept	For NRA representatives responsible for evaluation of clinical data
Clinical Trial Authorization Jakarta, Indonesia	1-5 Dec	English	14	15 Oct	NRAs sending representatives to "CTA" course must document that there are clinical trials conducted in the country, that the NRA has implemented or is in the process of implementing the legal/regulatory framework to authorize clinical trials.

Designing Courses for Learning TBD (AMRO)	TBD	English	15	TBD	By invitation only (AMRO)

Please note that in the event we do not have enough participants, the course may be postponed or cancelled.

World Health Organization

GLO/VQ Global Learning Opportunities for Vaccine Quality

2015

Learning opportunities

Course	Dates	Language	Max number of participants	Application deadline	Comments
GCP Inspection Cape Town, South Africa	TBD Jan 2015	English	14		NRAs sending representatives to "GCP inspection" course must document that the NRA has the legal/regulatory framework in place to authorize clinical trials and to perform inspections once the trial is started.
Designing Courses for Learning TBD (AMRO)	TBD Early 2015	English	15		By invitation only (AMRO)
Legislation of Clinical Data	TBD June 2015	English	14		PAP countries
e-VVM-based Vaccine Management (NEW)		English	15	n/a	The course takes 9 weeks to complete. For course details please go to:http://epela.net/epela_web/evvm.html. For applying online, please go to:http://epela.net/epela_web/apply_online_evvm.html
e-Pharmaceutical Cold Chain Management		English	15	n/a	The course takes 11 weeks to complete. For course details please go to:http://epela.net/epela_web/introduction.html. For applying online, please go to: http://epela.net/epela_web/apply_online.html
GCP Inspection Jakarta, Indonesia		English	14		NRAs sending representatives to "GCP inspection" course must document that the NRA has the legal/regulatory framework in place to authorize clinical trials and to perform inspections once the trial is started.
Pharmaceutical Cold Chain Management on Wheels In association with Tip Kurumu, Turkey		English	15		NRA representatives of vaccine producing countries, supply, packaging and distribution unit, representatives from WHO prequalified vaccine manufacturers, representatives from PQS prequalified manufacturers and pharmaceutical industry
Facilitation Skills Antalya, Turkey		English	15		By invitation only
Evaluation of Clinical Data Jakarta, Indonesia		English	14		For NRA representatives responsible for evaluation of clinical data
Clinical Trial Authorization Jakarta, Indonesia		English	14		NRAs sending representatives to "CTA" course must document that there are clinical trials conducted in the country, that the NRA has implemented or is in the process of implementing the legal/regulatory framework to authorize clinical trials.

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