






# Course Schedule 2023




## Clinical Operations courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Advanced Clinical Project Management <sup>8</sup> 	Classroom	Brussels			23, 24							16, 17		
	Webinar	Online					22, 24, 26, 30, 01, 02							
Budgeting Clinical Studies 	Classroom	Brussels						22						
Clinical Project Management <sup>9</sup>	Webinar	Online			8, 10, 15, 17									
	eLearning + Classroom	Online + Brussels											7	
		Online + Zurich					12							
Clinical Research Training for Junior Clinical Research Associates <sup>2</sup>	Webinar	Online					02, 04, 09, 11							
	Classroom	Brussels							06, 07		27, 28			
		Leiden												14, 15
Clinical Research Training for Senior Clinical Research Associates <sup>1</sup>	Webinar	Online				24, 26								
	eLearning + Classroom	Online + Brussels										9		
Computer System Validation for Clinical Operations	Webinar	Online			20, 22									
	Classroom	Brussels										23, 24		
CRO Management and Oversight <sup>8</sup>	Webinar	Online						06, 08, 13, 15						
	Classroom	Brussels										18, 19		
Decentralised Clinical Trials - From Theory to Practice 	Classroom	Brussels										17, 18		
Designing clinical research protocols for a better outcome	eLearning + Classroom	Online + Brussels			30									
Getting the Right Level of Sponsor Oversight 	Webinar	Online						19						
	Classroom	Brussels										18		
Importance of the Involvement of Clinical Operations in Clinical Study Protocol Review <sup>8</sup>	Webinar	Online						19				20		
Keeping oversight of Data Management for Clinical Project Managers 	Webinar	Online										23		
Risk-Based Monitoring <sup>2</sup>	eLearning + Classroom	Online + Brussels										11		
	Webinar	Online					03, 05							
Risk Management in Clinical Research <sup>1</sup>	eLearning + Classroom	Online + Brussels											8	
	Webinar	Online			15, 17									

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.

# Course Schedule 2023

## Clinical Operations courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Introduction to Clinical Research <sup>2</sup>	eLearning	Online												
Introduction to Clinical Research with Medical Devices <sup>3</sup>	eLearning	Online												
Managing the Trial Master File and basics of Clinical Trial Systems 	Classroom	Brussels							7					
People Management	Classroom	Brussels											9	
	Webinar	Online			29, 31									
Running Medical Device Studies <sup>3</sup>	Classroom	Brussels						27, 28					21, 22	
Sponsor Co-Monitoring <sup>1</sup>	Webinar	Online					08, 10							
	Classroom	Brussels										10		
Advanced Clinical Researcher STAR Programme <sup>1</sup>	Classroom	Brussels										9, 10, 11		
	Webinar	Online				24, 26	03, 05, 08, 10							
Advanced Project Management STAR Programme <sup>8</sup>	Classroom	Brussels										16-20		
	Webinar	Online					22, 24, 26, 30	01, 02, 06, 08, 13, 15, 19						
Clinical Project Management STAR Programme <sup>9</sup>	Classroom	Brussels											6-9	
	Webinar	Online			8,9,15, 17, 22, 24, 29, 31									
Clinical Trial Assistant STAR Programme 	Classroom	Brussels							6					
Junior Clinical Researcher STAR Programme <sup>2</sup>	Classroom	Brussels							5-7		26-29			
		Leiden												12-14
Medical Devices STAR Programme <sup>3</sup>	Classroom	Brussels						26-28					20-22	
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)														
Budgeting Clinical Trials	Upon Request													
Monitoring and Protocol Deviation	Upon Request													
GMP Essentials for Clinical Operations Staff	Upon Request													
Remote Monitoring and Opportunities during COVID-19 and Beyond	Upon Request													
Introduction to Pediatric Clinical Development 	Upon Request													
The ECG in Clinical Research	Upon Request													
Transfer of Sponsorship of ongoing trials	Upon Request													
Safeguarding Data Integrity in Highly Regulated Environments	Upon Request													
What's new with ISO 14155:2020 GCP	Upon Request													
Introduction to Statistics	Upon Request													

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.

# Course Schedule 2023

## Clinical Research courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Bridging preclinical and clinical development	Classroom	Brussels											27, 28	
	Webinar	Online					02,04 09,11							
Data Protection in Clinical Research and GDPR in action	Classroom	Brussels						20						
Drug Development Cycle	eLearning	Online												
Introduction to Oncology for Clinical Researchers	Classroom	Brussels										26, 27		
Legal Basics for Clinical Study Contracts <sup>9</sup>	Classroom	Brussels											6	
	Webinar	Online			22, 24									
Orienting your Career in Clinical Research <sup>2</sup>	Classroom	Brussels							5		26			
	Classroom	Leiden												12
How to prepare your vaccine candidate for clinic	Classroom	Brussels			28									
Keeping oversight of safety for Clinical Project Managers	Webinar	Online						27				24		
Pharmacovigilance System Compliance - Medical Product Life Cycle	Classroom	Brussels			20, 21									
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)														
Clinical Development of a Vaccine	Upon request													
Data Management Essentials for Clinical Project Managers	Upon request													
Implementing GDPR in your organisation	Upon request													
ISO14155 Training <sup>3</sup>	Upon request													
Critical Literature Review	Upon request													
Data Management Essentials for Clinical Project Managers	Upon request													
Effective Medical Writing & Data Presentation	Upon request													
Introduction to Statistics	Upon request													
Laboratory Testing in Clinical Research	Upon request													
Learning Journey on Drug Development	Upon request													
Recist Training	Upon request													
Writing Procedural Documents	Upon request													

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.



# Course Schedule 2023



## Quality Assurance courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
A Risk-Based Approach to Clinical Audits	Classroom	Brussels						21						
Audit and System Inspection Readiness - How to be prepared <sup>1 5 8</sup>	Classroom	Brussels						14						
Auditing Clinical Development Documents <sup>5</sup>	Webinar	Online						15						
Clinical Service Provider Audits <sup>4</sup>	Classroom	Brussels						22						
Communication and Appreciative Auditing <sup>5</sup>	Webinar	Online						16						
Introduction to System Audits for Clinical Auditors <sup>4</sup>	Classroom	Brussels						19						
Introduction to Regulatory Affairs	Webinar	Online									14			
Introductory Course on Auditing Investigator Sites <sup>5</sup>	Classroom	Brussels						12, 13						
Writing Audit Reports <sup>4</sup>	Classroom	Brussels						20						
<b>Advanced Auditors STAR Programme<sup>4</sup></b>	<b>Classroom</b>	<b>Brussels</b>						19-22						
<b>Junior Auditors STAR Programme<sup>5</sup></b>	<b>Classroom</b>	<b>Brussels</b>						12, 13, 14						
	<b>Webinar</b>	<b>Online</b>						15, 16						
<b>The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)</b>														
Remote Auditing	Upon request													

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.

# Course Schedule 2023

## Regulatory courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Basics on Regulatory Requirements in Clinical Research <sup>2</sup>	eLearning	Online												
Clinical Research Training for Clinical Trial Assistants (CTAs)	Classroom	Brussels											13	
Foundational ICH-Good Clinical Practice (GCP) E6 (R2) Training <sup>2</sup>	eLearning	Online												
GCP Essentials in 90 Minutes	eLearning	Online												
Good Manufacturing Practice (GMP) in relation to GCP	eLearning	Online												
ICH-GCP E6 (R2) Refresher	eLearning	Online												
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Biometrics Staff	eLearning	Online												
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Clinical Operations Staff	eLearning	Online												
ICH-Good Clinical Practice (GCP) E6 (R2) for Investigators	eLearning	Online												
Implementation of MDR 2017/745 in Belgium	eLearning	Online												
Impact of the EU CTR 536/2014 on your organisation 	Webinar	Online				27								
Introduction to Regulatory Affairs 	Webinar	Online									14			
Clinical Investigations: Implementation of MDR 2017/745 in Belgium	Webinar	Online				20								
How to cope with the development of drug-device combinations?	eLearning	Online												
ICH-GCP E6 (R2) Refresher + Complementary ICH-GCP Refresher for Regulatory Staff <sup>5</sup>	eLearning	Online												
Local Clinical Trial Legislation in the USA <sup>5</sup>	eLearning	Online												
Medical Device Regulations <sup>3</sup>	Classroom	Brussels						26					20	
Orienting your Career in Regulatory Affairs	Classroom	Brussels						22						
The Belgian Clinical Trials Law of 2017: A Clear View on Rules	Webinar	Online			27							12		
The European Clinical Trial Directive for Medicinal Products <sup>6</sup>	eLearning	Online												
The European Clinical Trial Regulation (CTR) 536/2014 <sup>6</sup>	Webinar	Online						20					16	
Understanding and complying with the EU CTR	Webinar	Online					23, 25							12, 14
	Classroom	Brussels		28								5		
Clinical Regulatory STAR Programme <sup>6</sup>	Webinar	Online						20					16	
Regulatory Affairs STAR Programme <sup>7</sup>	Classroom	Brussels									18-22			
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)														
Ready for the IVDR? Regulatory impact and milestones for CE marking	Upon request													
Clinical Investigations: Implementation of MDR 2017/745 in Belgium	Upon request													
European Legislation for Clinical Research – Implementation in Belgium	Upon request													
How to cope with the development of drug-device combinations?	Upon request													
Good Clinical Laboratory Practice	Upon request													
Good Manufacturing Practice (GMP)	Upon request													
Good Distribution Practice (GDP)	Upon request													

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.



# Course Schedule 2023

## Soft Skills courses

COURSE NAME	FORMAT	LOCATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Communication Skills <sup>2</sup>	Classroom	Brussels									29			
Line Management Essentials	Classroom	Brussels										26, 27		
People Management <sup>3</sup>	Webinar	Online			29, 31									
	Classroom	Brussels											9	
Career Launch Coaching (flexible schedule)	Webinar	Online	Upon your agenda											
Clinical Career Coaching (flexible schedule)	Webinar	Online	Upon your agenda											
The following courses aren't scheduled but can be requested as a tailored course (choose topic, location, number of participants and format)														
Change Management for Clinical Research	Upon request													
Communicating with EU Regulators/Health Authorities	Upon request													
Enhancing your Communication and Presentation Skills in the changing Clinical Trial world	Upon request													
Influencing skills	Upon request													
Leading in a Solution Focused Way	Upon request													
Stress Prevention at Work	Upon request													
Time Management	Upon request													
Microsoft Project Basics for Clinical Project Managers	Upon request													
Intercultural Communication Skills	Upon request													
Remote Team Management : How to successfully lead	Upon request													
Train the Trainer	Upon request													
Female Leadership in Clinical Research	Upon request													

\*Courses followed by numbers in upper script are the training sessions included in a specific STAR Programme.