HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for
The new Clinical Trial Regulation explained… break-time sessions to ease your transition!

11 am – 12 pm, Monday 22 November to Thursday 25 November 2021

DATE	TOPIC	PRESENTER
Monday 22 Nov	**Opening remarks**	Grainne Power, Director of Human Products Authorisation and Registration, HPRA
	General principles and new concepts	
	General principles - CTR vs Directive	Elaine Breslin, Clinical Assessment Manager, HPRA
	New concepts – Overview of the authorisation processes, RMS and MSC roles	Shane Gormley, Clinical Assessor, HPRA
	Clinical Trials Information System (CTIS)	Kiara Murphy, Case Administrator, HPRA
Tuesday 23 Nov	**Post-authorisation, transition and how can I prepare?**	
	Safety monitoring and reporting	Sandra Bright, Clinical Assessor, HPRA
	Post authorisation – substantial modifications and notifications	Shane Gormley, Clinical Assessor, HPRA
	How do I transition my trial to the CTR?	Shane Gormley, Clinical Assessor, HPRA
Wednesday 24 Nov	**Ireland – how we will implement**	
	National implementing SI - principles	Colm O'Loughlin, Department of Health.
	Clinical trials in Ireland – authorisation process	Elaine Breslin, Clinical Assessment Manager, HPRA
	NREC-CT: Enabling Ireland's transition to harmonised assessment under the CTR	Aileen Sheehy, Programme Manager, National Office for Research Ethics Committees

Thursday 25 Nov	**Compliance aspects**	
	Serious breaches	Norah Cassidy, GCP/PV Inspector, HPRA
	GCP inspections - changes brought about by the CTR	Peter Twomey, GCP-PV Inspection Manager, HPRA
	IMP manufacture and labelling	Paul Sexton, GMP Policy Manager, HPRA and Peter Twomey, GCP-PV Inspection Manager, HPRA
	Close of event	Grainne Power, Director of Human Products Authorisation and Registration, HPRA