In association with

HRB Trials Methodology Research Network (HRB-TMRN)

Investigator Responsibilities for HPRA Regulated Studies

Durkan Theatre, Trinity Centre, St James' Hospital, Dublin 30th January 2015

Register @ http://bit.ly/1BAuM6Q

9:00 am	**Registration opens**	
	Chair	*Professor Pat Murray, Director UCD CRC*
9.30	**Welcome**	**Professor Declan Devane, HRB-TMRN**
9.35	**Opening Address**	**Dr Graham Love, Chief Executive, HRB**
9.45	**What to Expect from a Regulatory Inspection - Clinical Trials (Medicines)**	**Ms Deirdre O'Regan, GCP/ Pharmacovigilance Inspection Manager, HPRA**
10.15	**Trial Set-up**	**Ms Deirdre Hyland, RCSI CRC**
10.40	**Data Management**	**Dr Evelyn Flanagan, Data Manager, HRB CRF-C**
11.05-11.25	**Coffee**	
	Chair	*Professor Martin O'Donnell HRB CRF-G*
11.25	**Biorepositories**	**Dr Eoin Cotter, Head Scientific Services, UCD CRC**
11.50	**IMP/Placebo Sourcing, Release, Storage, Reconciliation.**	**Ms Caroline Whiriskey, Pharmacy Clinical Trials Unit, HRB CRF-G**
12.10	**Investigator's Viewpoint**	**Prof Brian Lawlor, PI Nilvad Study**
12.30	**Monitoring and Auditing**	**Dr Ruben Keane, Quality Manager, HRB CRF-C**
12.50	**Pharmacovigilance Requirements**	**Dr Muiris Dowling, Clinical Research Reporting Officer, HRB CRF-C**
1.10-2.10	**Lunch**	
	Chair	*Professor Michael Gill, Director HRB CRF-SJH*
2.10	**Academic Sponsorship**	**Ms Audrey Huggard, UCC Office Corporate & Legal Affairs**
2.40	**Strengthening trial methodology and reporting in Ireland - HRB-TMRN**	**Professor Declan Devane, Health Research Board-Trials Methodology Research Network (HRB-TMRN)**
2.50	**Regulatory Viewpoint, Clinical Investigations (Medical Devices)**	**Ms Marie Carleton, Clinical Assessment and Policy Manager/Medical Devices Lead, HPRA**
3.15	**Data Protection, Common Pitfalls**	**Ms Mairead Ashe, Data Protection Officer, HIQA**
3.40	**Biostatistics for Regulated Trials**	**Dr Erika Daly, Senior Manager Biostatistics, ICON Clinical Research**
4.05	**HRB/EI Irish Clinical Trials Research Network**	**Dr Fionnuala Keane, Development Lead ICTRN**
4.15	**Wrap-up & Meeting Adjourns**	**Professor Joe Eustace, Director CRF-C**

Contact: HRB-TMRN@nuigalway.ie

CPD points pending

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