Clinical Investigations & Performance Studies in Ireland under the MDR/IVDR

October 12th, Dublin

	Presenter	Time
REGISTRATION AND COFFEE		9:30
Welcome	**Olive O'Driscoll, Chairperson. Clinical Industry Liaison Officer, National Clinical Trials Office (NCTO)**	**10:00**
Opening Address	Dr Sinead Keogh, Head of Sectors at Ibec	10:05
Irish Medtech Skillnet	Mary Kane, Operations Network Manager, Irish Medtech Skillnet - Ibec	10:10
Introduction and Welcome from HPRA	Dr Donal O'Connor, Clinical Manager Medical Devices, HPRA	10:15
Overview of agenda and plan for day	Olive O'Driscoll, Clinical Industry Liaison Officer, NCTO	10:20
Session 1: Overview of Irish Review System	**Chair: Garrett Murray, Head of Life Sciences, Enterprise Ireland**	**10:25**
Introduction to EU regulations and HPRA process	Dr Donal O'Connor, Clinical Manager Medical Devices, HPRA	10:30
Submitting an Application to the National Research Ethics Committee for Medical Devices and In Vitro Diagnostic Devices	Chita Murray, Programme Manager (Interim) for the National Research Ethics Committee for Medical Devices	10:45
Session 1: Q&A		11:05
COFFEE & NETWORKING		**11:20**
Session 2: Clinical Investigations in Ireland	**Chair: Prof Martina Hennessy, Director of the Wellcome HRB CRF at St James's Hospital**	**11:35**
Medical Device Clinical Investigations at the HRB Clinical Research Facility St James	Derval Reidy, Jeremy Towns & Martina Hennessy, Wellcome HRB CRF at St James's Hospital	11:40
How does the HPRA assess clinical investigations?	Dr Gearóid McGauran, Medical Officer, HPRA	11:55
Pre-clinical requirements and risk management	Dhanashree Gokhale, Device Assessment and Surveillance Manager (Acting), HPRA	12:05
Study Design	Dr Gearóid O'Connor, Medical Officer, HPRA	12:15
Clinical Investigation Documentation	Dr Michele Meagher, Medical Officer, HPRA	12:35
Session 2: Q&A		12:50
LUNCH & NETWORKING		**13:05**

Session 3: Post approval requirements, IVDR and NCTO supports	**Chair: Dr Robert O'Connor, Director, NCTO**	**13:35**
Post Approval Requirements	Dr Ria Mahon, Medical Officer, HPRA	13:40
IVDR and Performance Studies	Dr Gearoid O'Connor, Clinical and Technology Assessor, HPRA	13:55
IVDR Performance Study in Ireland	Ausra Teiserskiene, Senior Clinical Project Manager at Cancer Trials Ireland	14:05
Clinical Industry Liaison Officer & National Clinical Trials Office	Olive O'Driscoll, Clinical Industry Liaison Officer, NCTO	14:25
Session 3: Q&A		14:35
COFFEE & NETWORK		**14:50**

Session 4: Medical Devices in Ireland: Patient and Company perspectives	**Chair: Olive O'Driscoll, NCTO**	**15:00**
Living with a Pacemaker	Rosemary Durcan, Resident at Founders, Dogpatch Labs	15:05
Clinical Investigations in Ireland; a Sponsor Case Study	Andrea Sauerland, Vice President Clinical Operations, Endotronix	15:20
Patient involvement and patient led product development and clinical trials - Empowering People with Parkinson's	Richelle Flanagan, CEO, My Moves Matter	15:40
Executing Post Market Clinical Follow-up Clinical Investigations in Ireland	Emma Meade, Director of Clinical Research, Neuromod Devices	15:55
Session 4: Q&A	Session 4 presenters & Donal O'Connor, HPRA, Clinical Manager Medical Devices, HPRA	16:10
Wrap Up and Close	**Olive O'Driscoll, Chairperson**	**16:25**

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