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An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Medical Device Regulation & Registries

Tom Melvin

NORE and EFORT standing committee

Brussels

6 April 2018

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Agenda

- Introduction
- Medical Device Regulation
- CIE Working Group
- Registries & Synergy

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Introduction

Medical Devices

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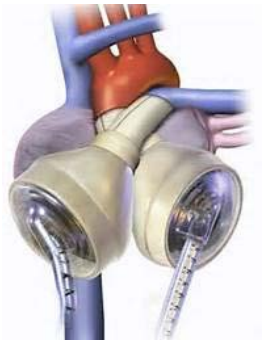

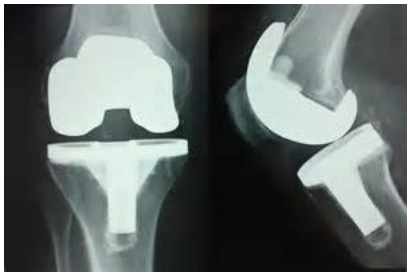

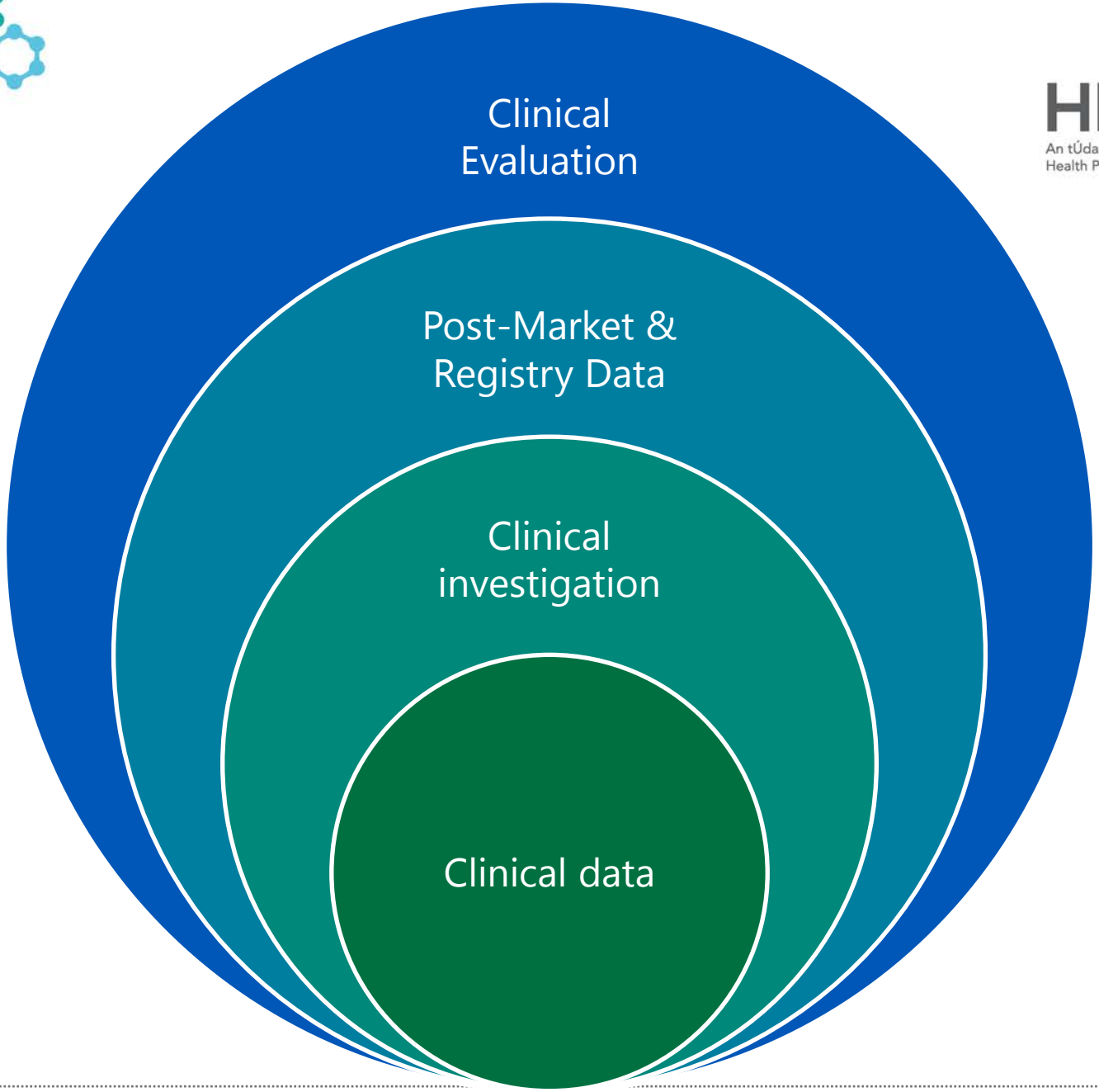
Clinical
Evaluation
Post-Market &
Registry Data
Clinical
investigation
Clinical data

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Medical Device Regulation

Changes with the MDR

- Size of Regulation
  - 23 – 123 Articles
  - 12 – 16 Annexes

- Legal Basis
  - Directive vs. Regulation
  - MEDDEV / ISO aspects incorporated

- Scope
  - AIMD
  - Annex XVI

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MDR - Snapshot

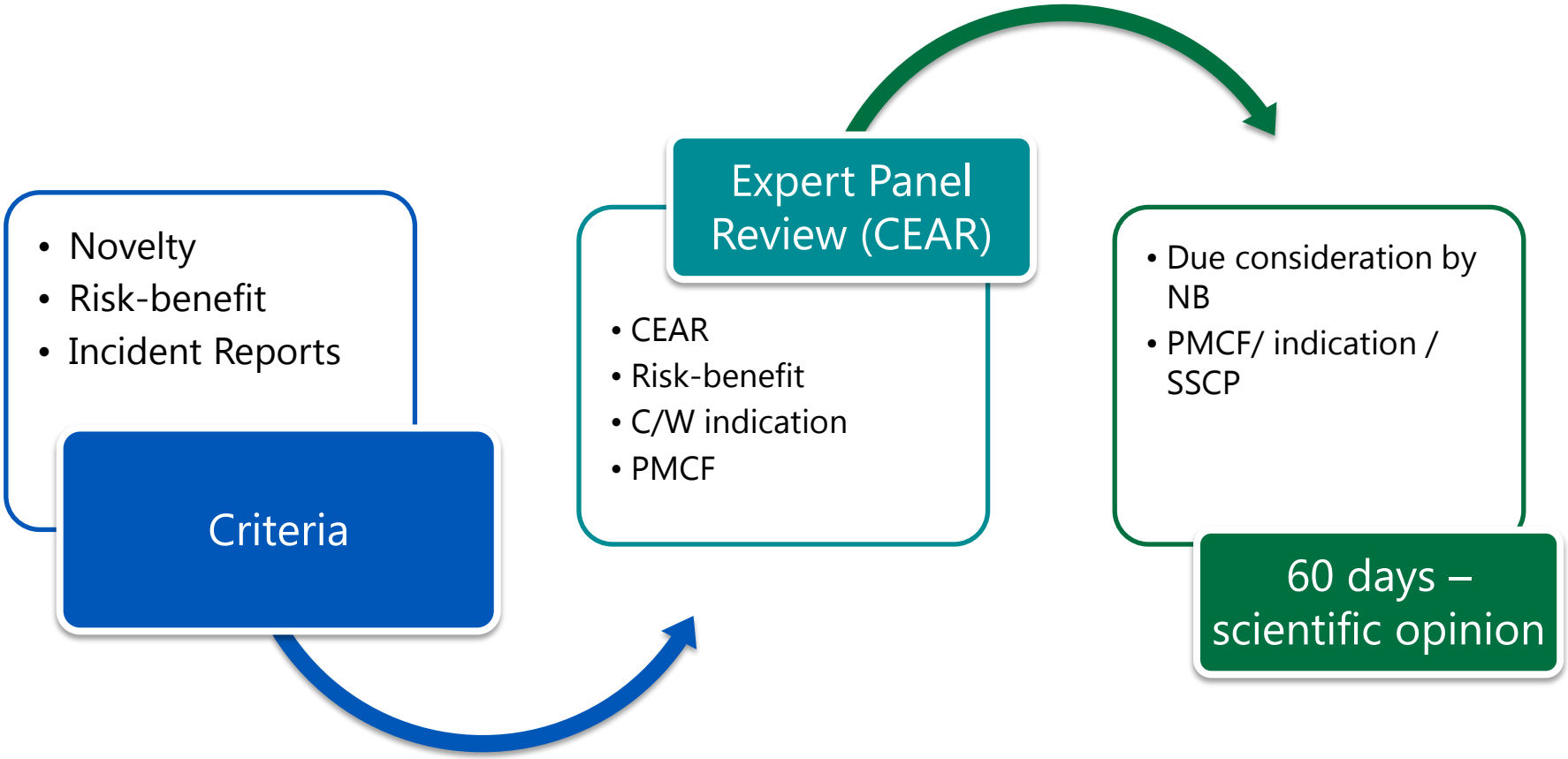
Common Specifications

Scrutiny

High risk devices

Equivalence

Clinical Evaluation Consultation – 'Scrutiny'



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MDR Implementation & CIE Working Group

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MDR Implementation Work Packages

1. Clinical Evaluation

2. SSCP

3. Template & Eudamed

4. CIE / IVD Taskforce

Terms of Reference

Work Package 1: Clinical Evaluation

Outputs - guidance on: equivalence & sufficient clinical data (Article 61(6)(a))

Members:

- IE/UK (lead), FR, SE, DE, NL
- TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTec Europe, ESC, COCIR

Timelines – TCs, kick-off meeting MHRA on 9th of February, drafts for public consultation 23 March, finalisation CIE 16-18 April

Work Package 2: SSCP

Outputs - Template and Guidance for SSCP

Members:

- SE (lead), DK
- EUROM VI, TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTec Europe, ESC, COCIR, EPF, CGJA

Timelines – TCs, first draft 8 Feb, kick-off meeting SE on 20 Feb, draft for public consultation 26 Feb, commenting period 26 March, finalisation CIE 16-18 April

Work Package 3: Template & MDR EUDAMED

Outputs

- Template development - CEAR (IE), CI application (BE, IE), CI assessment (UK, CH), PMCF plan and report (BE, IT), SAE (DE, NL)
- The Co-Ordinated CI Assessment Procedure (with a focus on template and EUDAMED functionality)(COM lead)
- Interaction between the CIE and EUDAMED WG

Members: above + EUROM VI, TEAM NB, NB MED, EUROMCONTACT, AESGP, MedTech Europe, ESC, COCIR, CGJA

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Call for Experts

Working Groups w.r.t. MDR

Issued by Commission

Expected in May 2018

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MDR & Registries

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What is a registry?

Generally, it is an **organised system** that collects and maintains structured records on a specific disease, medical product etc. for a specific **time** period and **population**

Range from ward based spreadsheet to large internationally harmonised registries

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Elements of a Device Registry

Observational vs. interventional

Clinical data vs. other data (for example simply to be able to identify patients with X device)

Use as intended vs. '**off-label**' use

Outcomes to be measured

Purpose of registry

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Registry design

Define the uncertainty to be studied

Long term outcome, sub-population etc.

Determine if a Registry is needed

Can passive PMS systems answer the research question?

Set a plan for data collection + analysis

Consider device iteration and other cofounders

Plan for data governance, sharing + transparency

Consider involving stakeholders early

Timing of outcome reports

Registries and the MDR

Registry data given specific emphasis in MDR

Annex VI - **Notified bodies** to take registry data into account w/ recertification review

Annex XIII - **Manufacturers** to review suitable registry data as part of their post-marketing obligations

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MDR & Registries: Synergy

European and other Registry Initiatives

PARENT (the cross-border PAtient REgistries iNiTiative), co-funded by the European Commission and a number of Member States

EUnetHTA - European network for Health Technology Assessment

International Medical Device Regulators Forum (**IMDRF**)

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Potential Use of Registry Data

- Initial CE marking
- Device tracking to patient level w/ FSCA
- Change to intended use
- PMS / PMCF
- Objective Performance Criteria - OPCs
- Breakthrough products

Integrating Registry Data and Regulation

Data Sharing

- Sharing with bodies responsible for safety: MFR / NB / NCA
- Sharing with other registries / researchers
- Harmonised core data set

Governance

- Conflict of interest and funding, and transparency
- Plan for data collection, processing

Clear roles and responsibilities

- Purpose of registry and data points collected
- Management plan for completeness, data-management, auditing etc.

Data protection and transparency of data

- Registry website? Level of access

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Thank You

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