Medical Device Regulations: Clinical Impact

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Agenda

Introduction

Medical Device Regulation

In Vitro Diagnostic Regulation

Implementation
Introduction
Medical Devices
Iterative development vs. disruptive development
Clinical Evaluation

Post-Market data

Clinical investigation

Clinical data
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
Medical Device Regulation
MDR – Clinical changes

Clinical evidence for high risk devices

The ‘scrutiny’ procedure

Common specifications

Summary of safety and clinical performance
Clinical Evaluation Consultation – ‘Scrutiny’

- Novelty
- Risk-benefit
- Incident Reports

Criteria

Expert Panel Review (CEAR)
- CEAR
- Risk-benefit
- C/W indication
- PMCF

Due consideration by NB
- PMCF/ indication / SSCP

60 days – scientific opinion
Competent Authority Market Surveillance

- Proactive
- Reactive

Common Specifications

- Absent / insufficient standard
- Clinical / technical guidance

Scrutiny

- Expert Panel
- High risk devices
In Vitro Diagnostic Device Regulation
IVD Directive

Require a Notified Body

Do not require a Notified Body
80-90%

IVD Regulation

Require a Notified Body
80-90%

Do not require a Notified Body
Implementation
CIE: MDR Implementation Work Packages

1. Clinical Evaluation
2. SSCP
3. Template & Eudamed
4. CIE / IVD Taskforce
Terms of Reference
Joint Action on Market Surveillance

- Member state communication
- Market surveillance co-operation
- Clinical resources
- Common specification prioritisation
Thank You