14TH ANNUAL
FDA INSPECTIONS SUMMIT

WCG FDANEWS

# Panel Discussion: EU-MDR: Final Push for Compliance by the May 26, 2020 Deadline

Moderator: **Brian Ludovico**, Executive Director, NSF Medical Device Regulatory Certification

Panelists:
**Karl Vahey**, Vice President Manufacturing Quality, Cardinal Health
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the **and** means more

# 14th Annual FDA Inspections Summit

## EU-MDR: Final Push for Compliance by the May 26, 2020 Deadline

***Ibim Tariah Ph.D***

*Vice President, EU MDR & IVDR Services*

*R&Q Solutions Inc.*

# EU-MDR: Final Push for Compliance - What is the Designation Status of your Notified Body?

- Medical Devices
  - **British business standards company BSI Assurance UK Ltd;**
  - **Italy's IMQ - Istituto Italiano Del Marchio Di Qualità S.P.A.;**
  - **Stuttgart-based DEKRA Certification GmbH;**
  - **Nuremberg-based TÜV and Rheinland LGA Products GmbH;**
  - **TÜV SÜD Product Service GmbH Zertifizierstellen, from Munich.**
- *In-vitro* Diagnostic Medical Devices
  - **Stuttgart-based DEKRA Certification GmbH.**

- https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

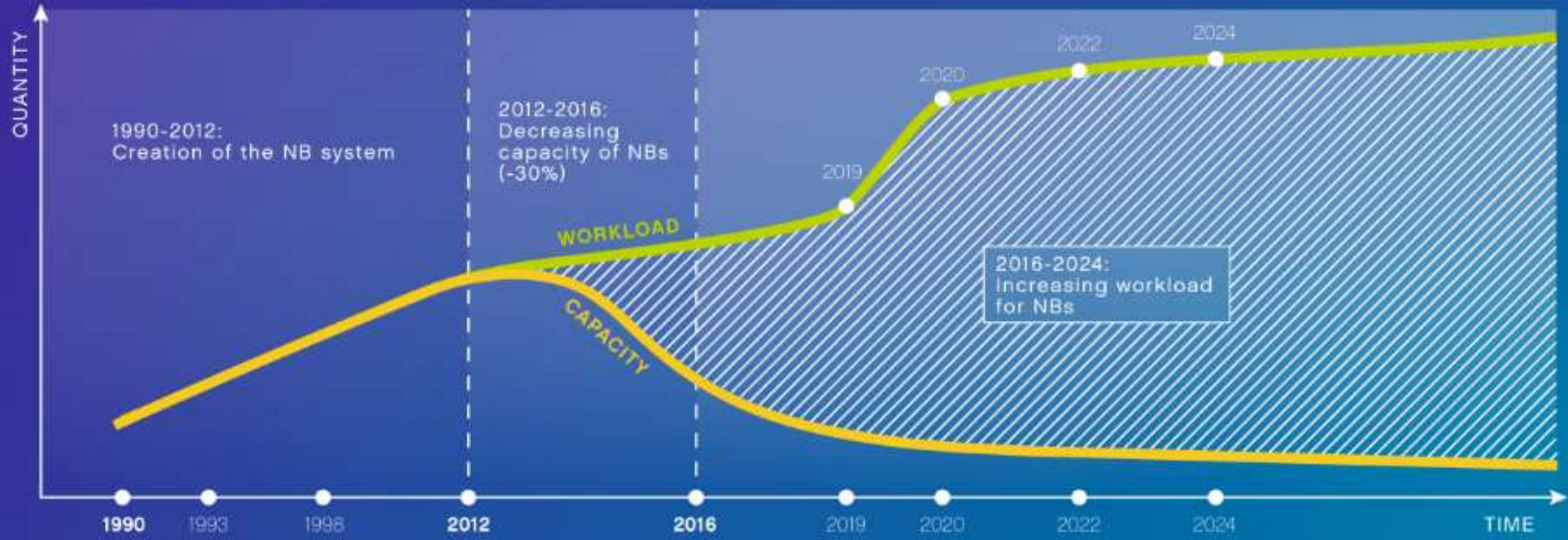
# An urgent need to close the gap

The involvement of Notified Bodies (NBs) in certifying medical technologies has evolved over the years and it is currently experiencing a significant revamp with the new CE Marking Regulations adopted in 2017.

This leads to a situation where less and less NBs have to manage more extensive work.

**The gap between Notified Body's capacity and the existing workload increases significantly. This needs to be urgently addressed by policymakers at EU level in order to guarantee a smooth continuation of supply of medical technologies to patients and healthcare systems.**

## NB Capacity vs Workload Over the Years



# What data do you have to support clinical performance claims?

- MDR Preamble…whereas (63)
  - **To ensure a high level of safety and performance, demonstration of compliance with the *general safety and performance requirements* laid down in this Regulation should be based on clinical data that, for class III devices and implantable devices should, as a general rule, be sourced from clinical investigations…..**

- MDR Article 2 – Performance Definition
  - **'performance' means the ability of a device to achieve its intended purpose as stated by the manufacturer;**

# What data do you have to support clinical performance claims?

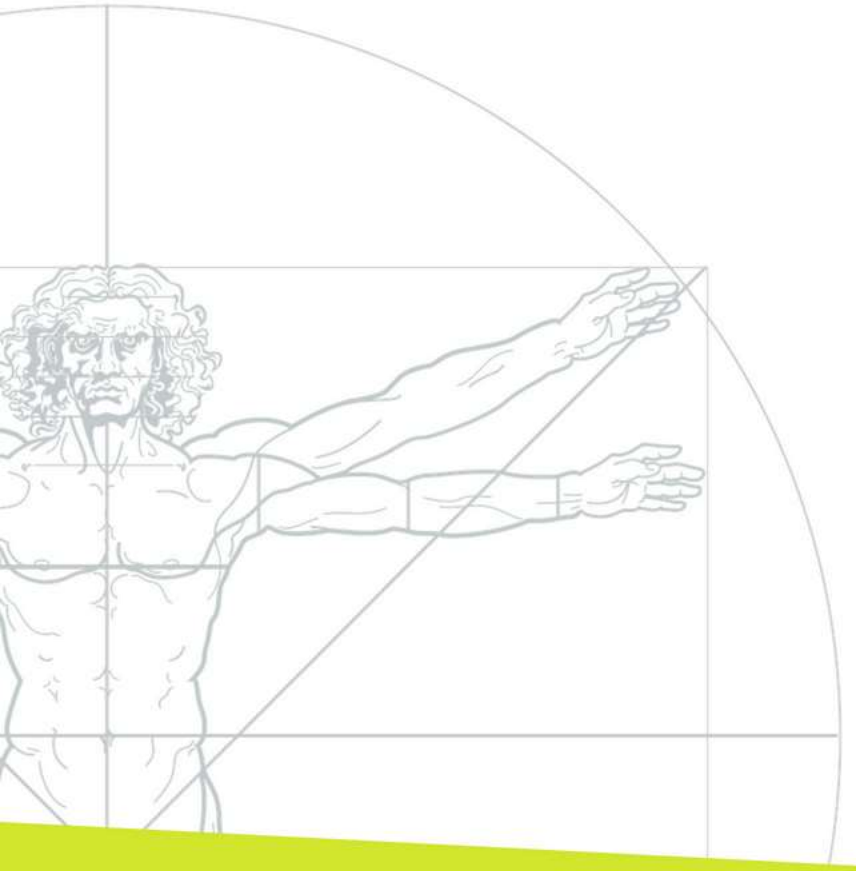
- MDR Article 2 - PMS Definition:
  - **‘post-market surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;**

# EU-MDR: Final Push for Compliance - What data do you have to support clinical performance claims?

MDR Post Market Surveillance Requirements:

- Post-market surveillance system of the manufacturer (Article 83)
- Post-market surveillance plan (Article 84)
- Post-market surveillance report (Article 85)
- Post Market clinical follow-up report (Article 61, 11; Annex XIV, Part B)
  - **For Class III devices and implantables devices the PMCF evaluation report and if indicated the Summary of Safety and Clinical Performance (SSCP, Article 32) shall be updated at least annually**
- Periodic safety update report (PSUR, Article 86)
- Summary of Safety and Clinical Performance (SSCP, Article 32)

the **and** means more



# Thank you!

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