AXON
science based lawyers

WIDELY RESPECTED ~ LIFE SCIENCES BOUTIQUE ~ CHAMBERS EUROPE 2021

MEDICAL DEVICES REGULATION AND VR

VR4REHAB
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health food technology

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Axon Lawyers and Erik Vollebregt

- Axon Lawyers is a medtech specialized law firm, with a lot of expertise and experience in M&A, investments, contracts, litigation and regulatory advice in (among others)
  - AI and software
  - Personal data concerning health, genetic data and biometric data
  - Imaging, imaging platforms, PACS systems and pathology platforms
  - 3D printing, modeling and customization of devices
  - Robotic surgery, surgical planning systems
- Erik Vollebregt: founding partner of Axon Lawyers, decades long background in EU and NL law in medtech (CE –> Call Erik) and pharma law and regulation

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VR and MDR / IVDR

- For fun – not a medical device
- For (clinical) training – not a medical device
- Providing information to be used in/for treatment or diagnosis – medical device (MDR)
  - For analysis of a human derived sample – in vitro diagnostic medical device (IVDR)
  - Direct diagnosis by software is not a requirement – providing information to inform treatment or diagnostic decisions is sufficient to qualify
- Drive or influence the use of a medical device (no medical intended purpose claimed)
  - E.g. VR app to control navigation of a medical device in the body, control or program a surgical robot

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MDR / IVDR guidance

- VR apps = software
- MDCG 2020-1 Clinical / performance evaluation of software
- MDCG 2019-11 Qualification and classification of software under MDR / IVDR
  - MDCG 2021-24 Guidance on classification of medical devices
  - MDCG 2020-16 Guidance on Classification Rules for IVDs
- MDCG 2019-16 Cybersecurity
- Other MDCG guidance relevant insofar as regulatory application

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MDR / IVDR

Clinical benefit

- It all starts with intended purpose
- Clinical evaluation / performance evaluation
  - What is the clinical benefit of the software?
    - Normally providing accurate medical information on patients, where appropriate, assessed against medical information obtained through the use of other diagnostic options and technologies
    - Clinical outcome for the patient is dependent on further diagnostic and/or therapeutic options which could be available
  - specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements (article 61 (1) MDR / 56 (1) IVDR) (sufficient amount + sufficient quality)
  - level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose (article 2 (51) MDR / 2 (36) IVDR)

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Some examples of clinical benefits

Reduction of pain and anxiety

In a recent pilot study, patients undergoing surgery at St George's Hospital in London had the option to use a VR headset prior to and during their operation to view calming landscapes during the procedure. 100% of the participants reported that their overall hospital experience was improved by wearing the headset, while 94% said they felt more relaxed. Furthermore, 80% said they felt less pain after wearing the headset and 73% reported feeling less anxious.

VR is also being used to help women get through labour pain, or what is known to be one of the most severe pains and the reason for pregnant women to opt for epidurals. VR is a viable alternative for those who would like to give birth naturally but without the worry of having a painful experience.

Physical therapy

Bringing a gamified approach to physical therapy for such patients is Neuro Rehab VR. Collaborating with physicians and therapists, the company develops VR training exercises with machine learning so as to tailor each exercise to patients' therapeutic needs. The aim is to make physical therapy more enjoyable so as to increase patient engagement.

Such methods have been proven to be indeed effective. In a study published last November, researchers found that after VR therapy, children with cerebral palsy experienced a significant improvement in their mobility. The authors of this study further called for adding this method to conventional rehabilitation techniques so as to improve outcomes.

Pain reduction

Rest and less pain in virtual reality thanks to medical devices from Healthy Mind VR

Every day we put a start-up in the spotlight. Today it's French company Healthy Mind, a start-up that aims to use therapeutic VR to reduce the use of medication for pain.

19 January 2022

CYRINE BEUNE

© Healthy Mind FR

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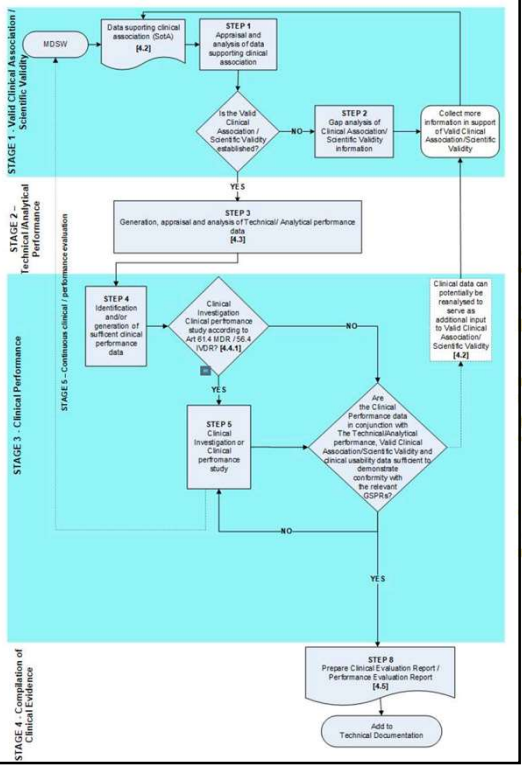
Generation of clinical evidence

- Process of clinical (MDR) / performance (IVDR) evaluation
  - Provide sufficient clinical evidence
    - Valid association (MDR) / scientific validity (IVDR)
      - Can you measure this way?
    - Technical performance (MDR) / analytical performance (IVDR)
      - Does it generate the output accurately, precisely and reliably?
    - Clinical performance (MDR + IVDR)
      - Does it yield clinically relevant output in accordance with the intended purpose?
  - Demonstrate conformity with GSPRs in Annex I based on clinical evidence



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Clinical evaluation of software

Model of Software	**CLINICAL EVALUATION** (MDR) / **PERFORMANCE EVALUATION** (IVDR) **- scope**
MDSW (with independent intended purpose and claimed CLINICAL BENEFIT)	MDSW only
MDSW (with intended purpose and claimed CLINICAL BENEFIT related to driving or influencing a medical device for a medical purpose)	MDSW and the driven or influenced medical device Notes 1,2
Software driving or influencing the use of a medical device (with no independent intended purpose or independent claimed CLINICAL BENEFIT)	Driven or influenced medical device including the software (component or accessory)

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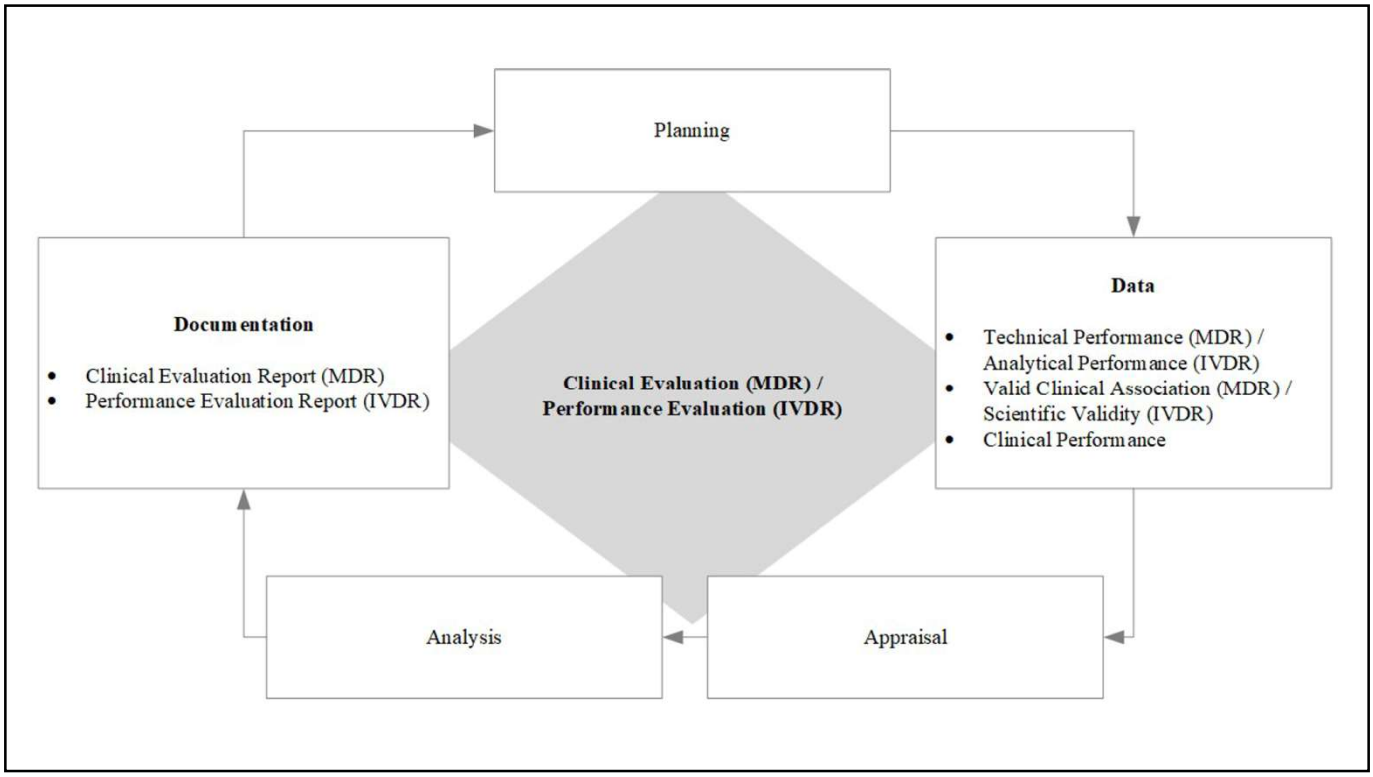

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GSPRs

- Risk reduction: Annex I 1-8 MDR and IVDR
- Interaction with environment: Annex I 14 MDR and Annex I 13 IVDR
- Devices with measuring function: Annex I 15 and Annex I 14 IVDR
- Software, network and cyber: Annex I 17 MDR and Annex I 16
- Active devices and devices connected to them: Annex I 18 MDR and Annex I 17 IVDR
- Devices for lay persons: Annex I 22 MDR and Annex I 19 IVDR (plus near patient testing)
- Labeling and IFU: Annex I 23 MDR and Annex I 20 IVDR

- Article 5 (5) MDR and IVDR – health institution exemption: no conformity assessments and CE marking but 'CE light'

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PMCF / PMPF

Schematically, this is how a system for post-market surveillance works:

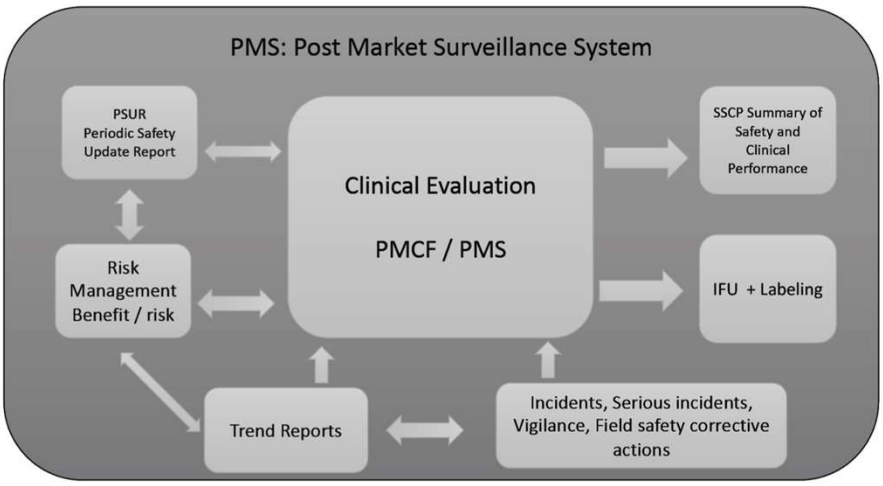

Figure 9 PMS system overview

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Other (highly relevant) EU legislation

- GDPR / ePrivacy regulation
  - Collection, processing and international transfer of personal data, with special attention to health data, genetic data and biometric data
- Draft AI Act
  - All software currently in scope of MDR and IVDR will also be regulated under AI Act requiring additional CE marking for AI Act Essential Requirements and obligations
  - MDR and IVDR health institution exemption does not apply to AI Act scope aspects
- Draft Data Governance Act
  - Gives patients more control over their data and regulating data exchange services, but also provides framework for data donation (e.g. for training AI or making VR models)
- European Health Data Space initiatives

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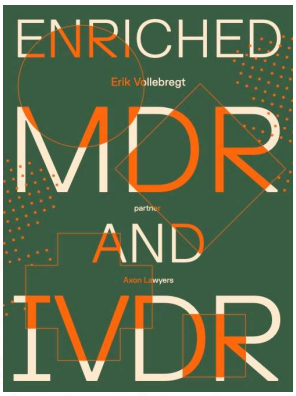
Thanks for your attention!



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