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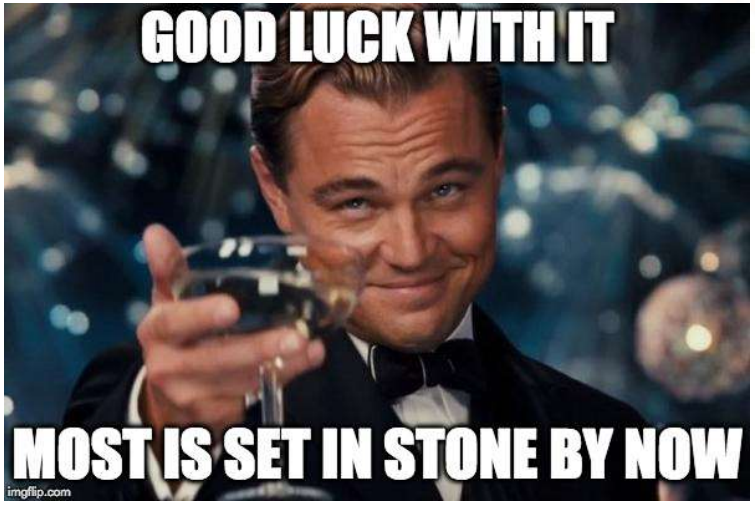
IVDR IN COVID-19 TIMES

health
food
technology

Erik Vollebregt
www.axonadvocaten.nl

Agenda

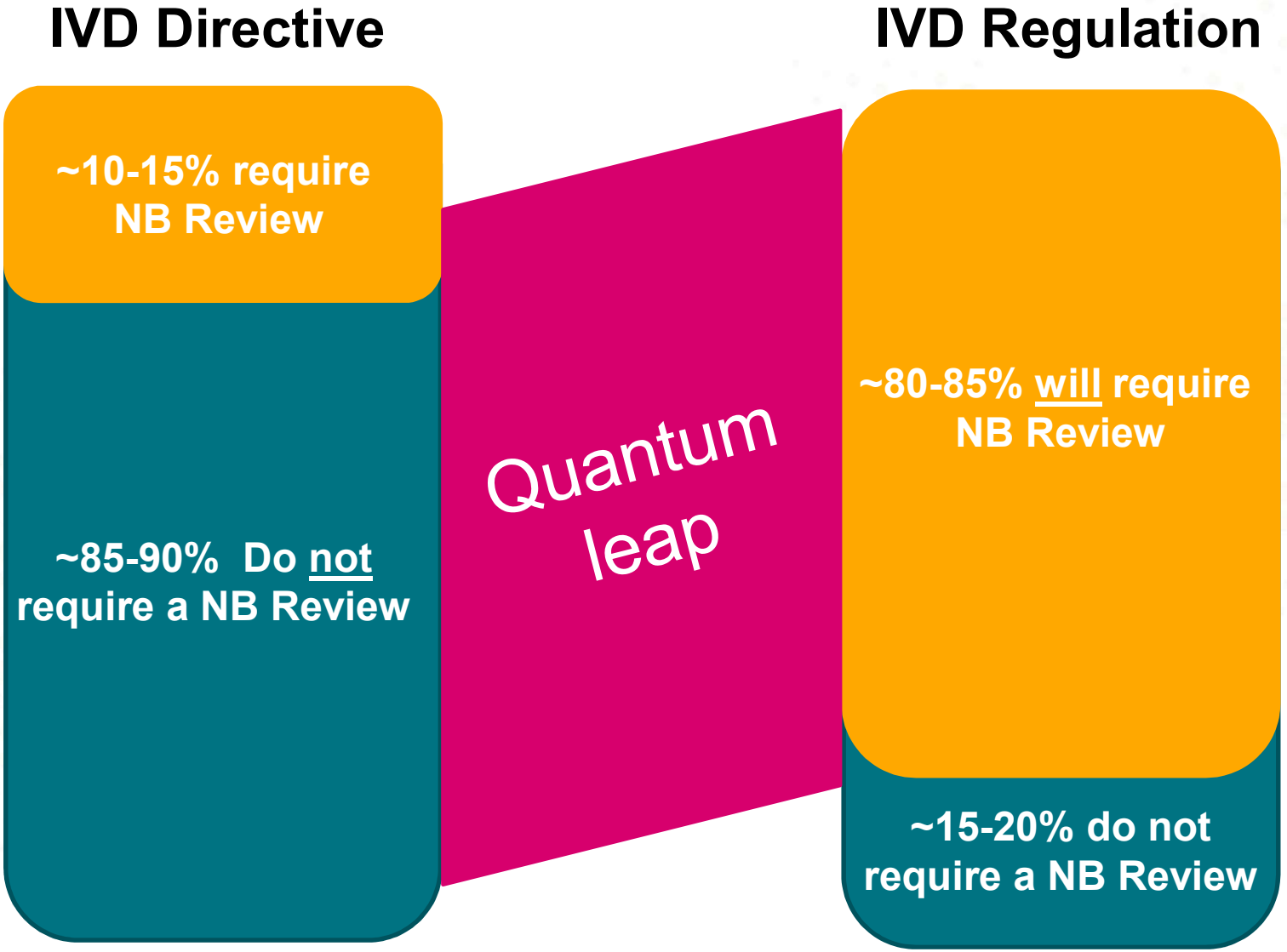
- Basic outline and timelines
- Supply chain implications
- Components specifications and maintenance
- Emergency guidance for IVD development
- Brexit, Swixit, Turkxit
- What is there still left to do until 26 May 2022?



No grandfathering and firm implementation deadlines

- All devices on the market are phased into the new system by the end of transitional period.
- This means that you **have to** do a new conformity assessment under the new rules for **all** devices currently on the market or remove the product from the market.
- If you don't have a new CE under IVDR, you cannot place new product on the market after transition period.

IVDR: a game-changer for IVDs



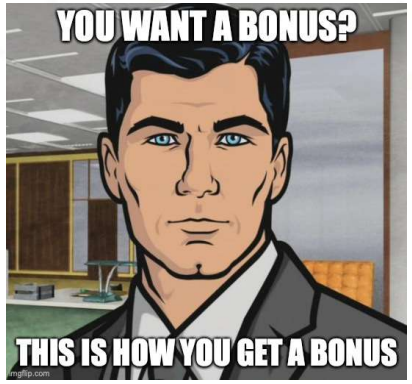
- **IVDR**: Brings a 780% workload increase for notified bodies (*source: MTE*)

GDPR and IVDR

- Combine to form a storm of storms for IVD industry
  - IVDR requires vastly more data for performance assessment and PMS, often from secondary use of samples.
  - IVDR requires compliance with GDPR for use of samples for regulatory purposes.
  - GDPR requires a big step up re use of personal data concerning health and genetic data.
    - Applies already to processing of personal data in performance data for IVDR readiness!
  - GDPR D-day: 25 May 2018

GDPR compliance required already

  - IVDR D-day: 26 May 2022



See GDPR bonus slides

Beantwortung der Frage: Was ist Aufklärung?

„Aufklärung ist der Ausgang des Menschen aus seiner selbst verschuldeten Unmündigkeit. Unmündigkeit ist das Unvermögen, sich seines Verstandes ohne Leitung eines andern zu bedienen. Selbst verschuldet ist diese Unmündigkeit, wenn die Ursache derselben nicht am Mangel des Verstandes, sondern der Entschließung und des Muthes liegt, sich seiner ohne Leitung eines andern zu bedienen. Sapere aude! Habe Muth, dich deines eigenen Verstandes zu bedienen! ist also der Wahlspruch der Aufklärung.

Faulheit und Feigheit sind die Ursachen, warum ein so großer Theil der Menschen, nachdem sie die Natur längst von fremder Leitung frei gesprochen (naturaliter majorennes), dennoch gerne Zeitlebens unmündig bleiben; und warum es Anderen so leicht wird, sich zu deren Vormündern aufzuwerfen. Es ist so bequem, unmündig zu seyn. Habe ich ein Buch, das für mich Verstand hat, einen Seelsorger, der für mich Gewissen hat, einen Arzt, der für mich die Diät beurtheilt, u. s. w, so brauche ich mich ja nicht selbst zu bemühen.

ales Band. Tg

European Commission

Transition Timelines

from the Directive to the *in vitro* diagnostic medical devices Regulation

IVDD Directive

Until 25 May 2022
All certificates issued under the *in vitro* diagnostic medical devices Directive (IVDD) are valid until their date of expiry

26 May 2022- 25 May 2024
certificates issued under the IVDD from 25 May 2017 expire latest by 27 May 2024

26 May 2024 - 27 May 2025
IVDD devices already placed on the market may continue to be made available

IVDR Regulation

From 26 MAY 2017
Devices that conform to the *in vitro* diagnostic medical devices Regulation (IVDR) may be placed on the market

From 26 MAY 2024
All devices placed on the marketmust be in conformity with the IVDR

26 MAY 2017 The **IVDR** enters into force

26 MAY 2022 The **IVDR** applies

2017 2018 2019 2020 2021 2022 2023 2024 2025

ACRONYMS
IVDD: Directive 98/79/EC **IVDR:** Regulation (EU) 2017/746

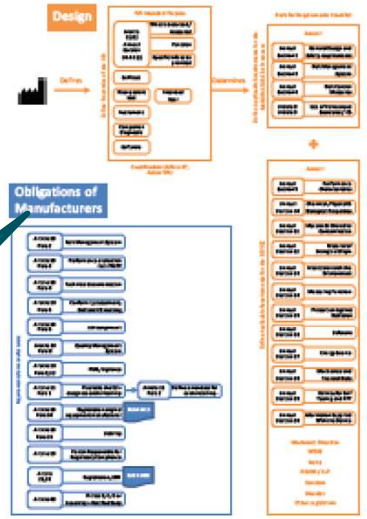
Health

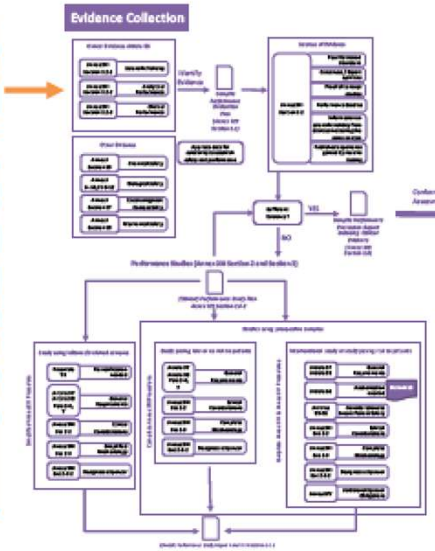
IVDR

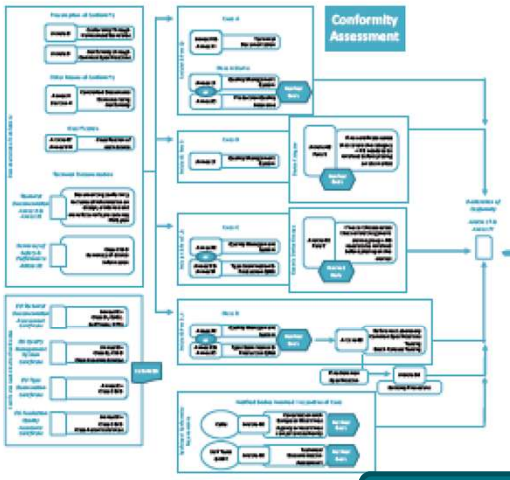
Contains new elements

Mostly new in terms of methods and data

Mostly new



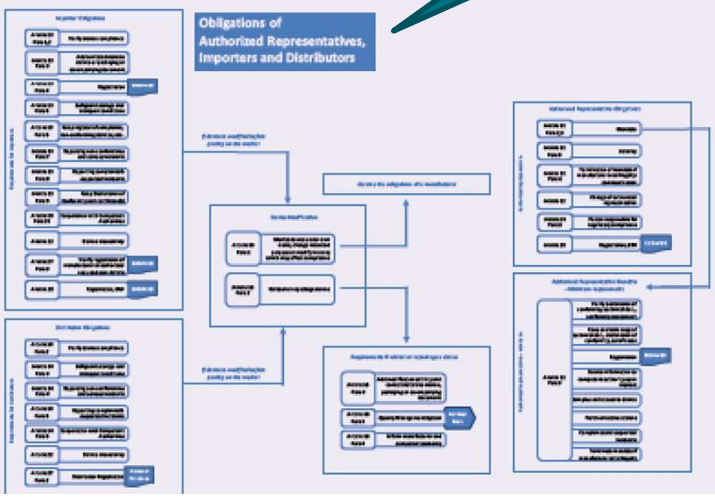




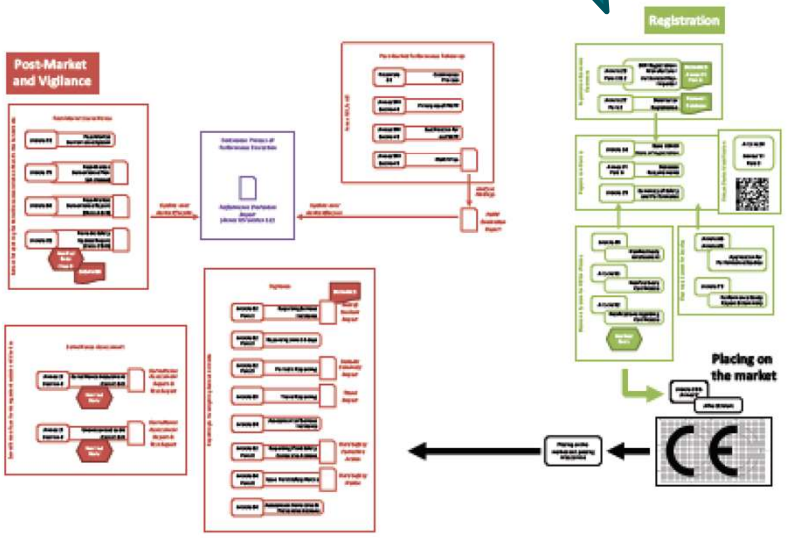
Contains some impactful new things

New

New



Contains many impactful new elements

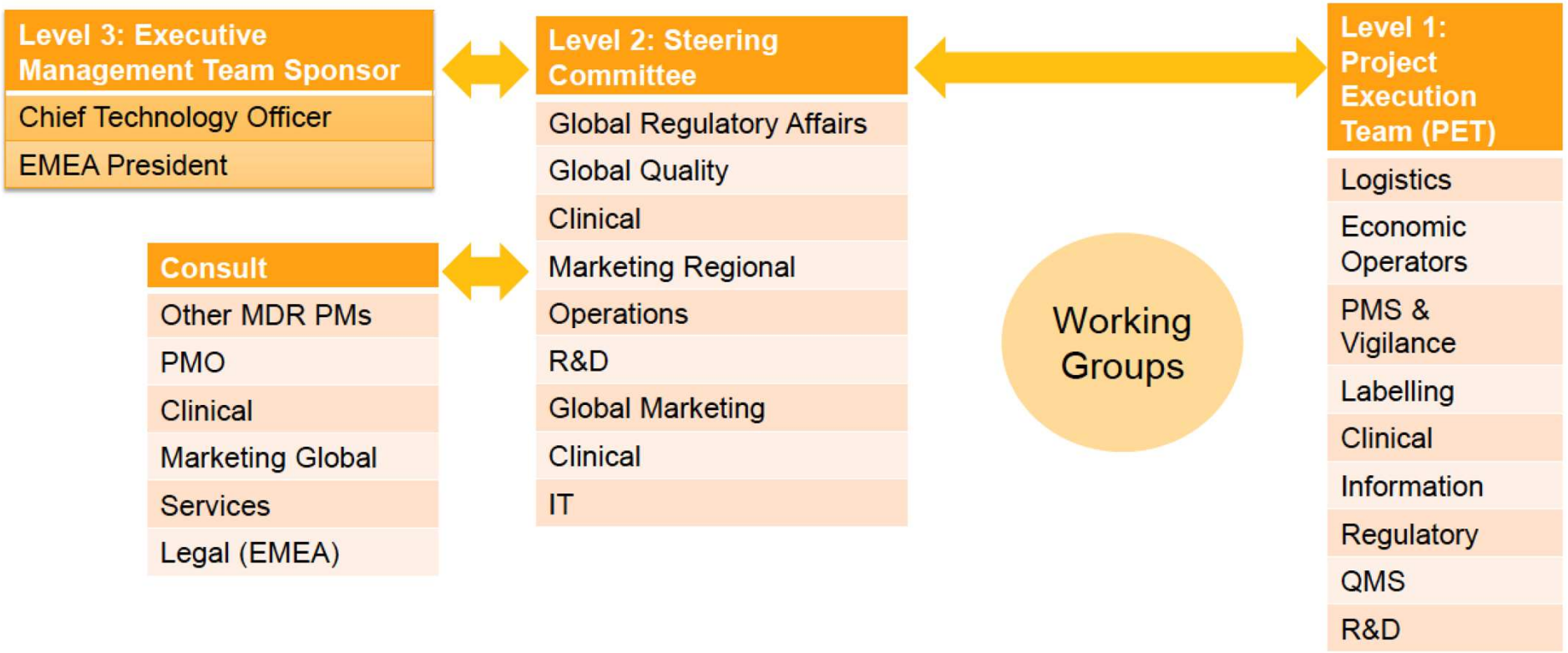


Gap assessment required

- MDR covered industry shows that this can an enormous and costly exercise for a company.
    - Plan, budget and execute.
- Impact of up-classification of devices in IVD industry much bigger than in MDR covered industry.
    - Many IVD companies will need a notified body for the first time and will have their documentation externally scrutinised.
- Generally QMS remediation gaps in IVD industry bigger.
    - IVDR requires ISO 13485:2016 “plus” QMS.

Gap assessment required

- Do not underestimate this project as it is critical to your presence on the EU market.



What is new?

- IVDR requires systematic lifecycle approach to compliance by requiring implementation of ‘systems’ and ‘plans’ (article 10).
- IVDR = Indeed Vast Data Really which needs to be fed back into device design, risk management and clinical evaluation quicker.
- Performance evaluation is at a much higher standard for IVDs.
- EUDAMED database will contain all economic operators and device UDIs.
- Companion diagnostics, self-tests and near patient tests are defined and regulated under IVDR.
- Increased design requirements for software.

What is new?

- Definitions
    - Many definitions are changed and have been added
        - Companion diagnostic, near-patient test, etc.
- Document and QMS requirements
    - Prescribed format for technical documentation, declarations of conformity, Post Market Performance Follow Up Plan, Risk Management Plan.
- Claims and advertising regulation
- New functions and changes to existing functions
    - Person responsible for regulatory compliance
    - Authorised representative heavily regulated and product liable

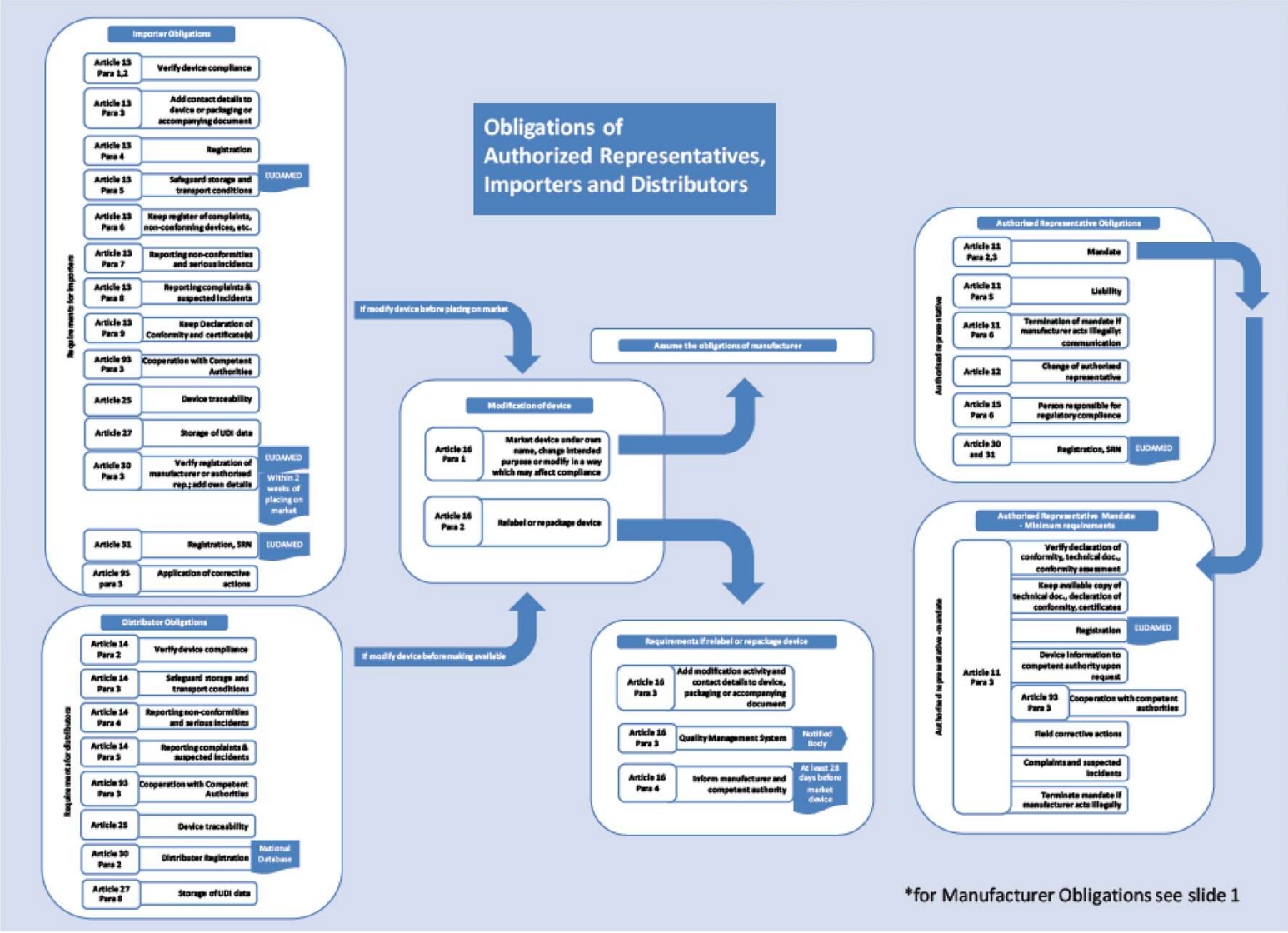
What is new?

- New risk classification system
- Regulation of MaaS (medical device as a service)
- New supply chain regime – economic operator
- Labeling, UDI and much more details label and IFU requirements
- Performance evaluation and clinical investigation
- Product liability rules changed
    - Insurance requirements (QMS item)
    - Facilitation of claims by competent authority
    - AR jointly and severally liable with manufacturer

What is new?

- New parts and components regime
    - Obligation of validation for part manufacturer
    - Performance changing parts are devices in themselves
- EUDAMED database
- Inhouse produced devices regime under IVDR
    - In-house production needs justification that required performance of device is not available commercially.

Economic operators regime based on old Reg 765/2008



How does this apply?

Manufacturer

- Places non-imported devices on the market

Importer

- Places imported devices on the market
- Established in the Union

Distributor

- Makes devices available
- Can be manufacturer (or not) under art. 16 conditions (branded distribution
- May put devices into service

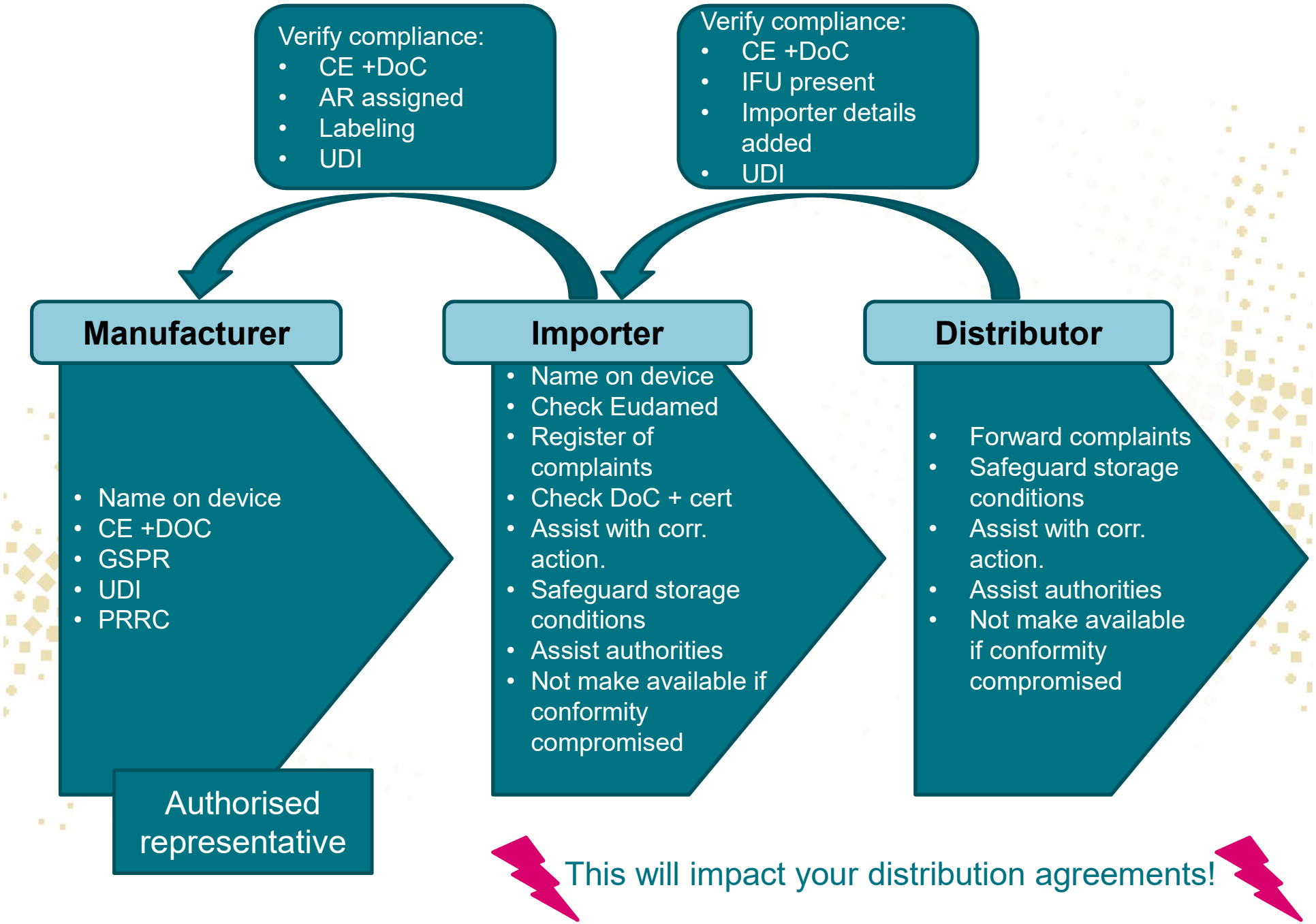
Authorised Representative

Clearance, logistics and storage providers

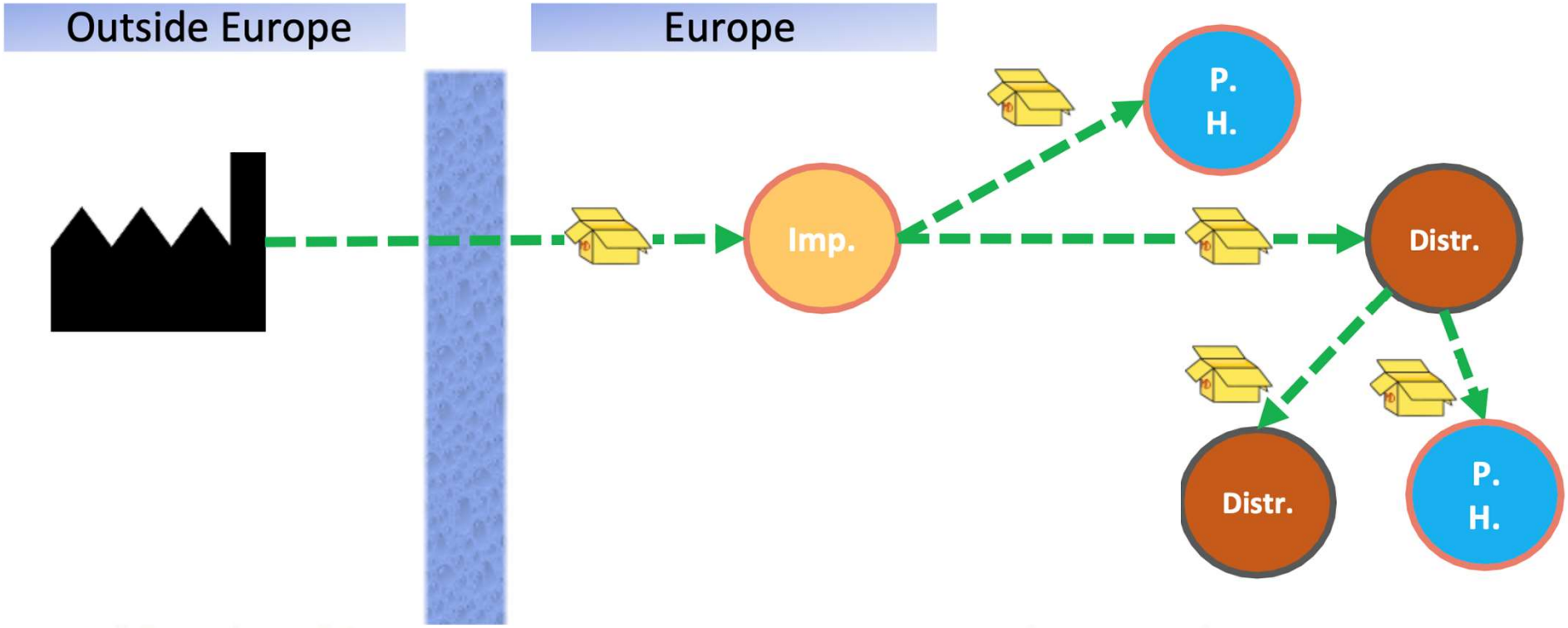
- Does not make devices available on own behalf

System integrator / procedure pack steriliser

- Has general EO obligations (e.g. UDI)


Verify compliance:
• CE +DoC
• AR assigned
• Labeling
• UDI
Verify compliance:
• CE +DoC
• IFU present
• Importer details added
• UDI
Manufacturer
• Name on device
• CE +DOC
• GSPR
• UDI
• PRRC
Authorised representative
Importer
• Name on device
• Check Eudamed
• Register of complaints
• Check DoC + cert
• Assist with corr. action.
• Safeguard storage conditions
• Assist authorities
• Not make available if conformity compromised
Distributor
• Forward complaints
• Safeguard storage conditions
• Assist with corr. action.
• Assist authorities
• Not make available if conformity compromised
This will impact your distribution agreements!

Map your supply chain to understand who is what



How does this apply?

Understanding of concepts of “placing on the market” and “making available” crucial for EO characterisation.

Placing on the market

- First transfer of a device from the manufacturing stage into the Union distribution chain after final quality control release as finished goods (includes packaging or labelling).
- The device must be freely available for supply or final use within the Union supply chain (customs cleared and intent to distribute in Union).

Making available

- device must be supplied for distribution, consumption or use in the Union in the course of a commercial activity, either for payment or free of charge.
- Implies offer or agreement, physical handover not required.

Challenges (just a few)

- Economic operators is QMS item depending on the notified body you ask

- What is placing on the market and making available?
- How to set up the AR in view of arm's length placement because of product liability risk?
- Importer labelling – how, what, where?
- How to equip/operationalise the PRRC?
- What is 'verification' and 'consider or have reason to believe'?
- How to pool resources to be made available to an intra-group chain of EOs? Can AR and MFR share PRRC resource etc.?
- How to cooperate between EOs on overlapping responsibilities?
- How to work with EO obligations in soft transition period of 2022-2024 for IVDR.
- Dealing with third parties that turn out to be importers or distributors (e.g. fulfilment houses – see Blue Guide).

Clinical evidence collection under IVDR: much more detail

Clinical evidence based on

- Scientific validity
- Analytical performance
- Clinical performance

(61) 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 evidence. It is necessary to clarify the requirements for the demonstration of the clinical evidence, that is based on data on scientific validity, and the analytical performance and clinical performance of the device. To allow for a structured and transparent process, generating reliable and robust data, sourcing and assessment of available scientific information and data generated in performance studies should be based on a performance evaluation plan.

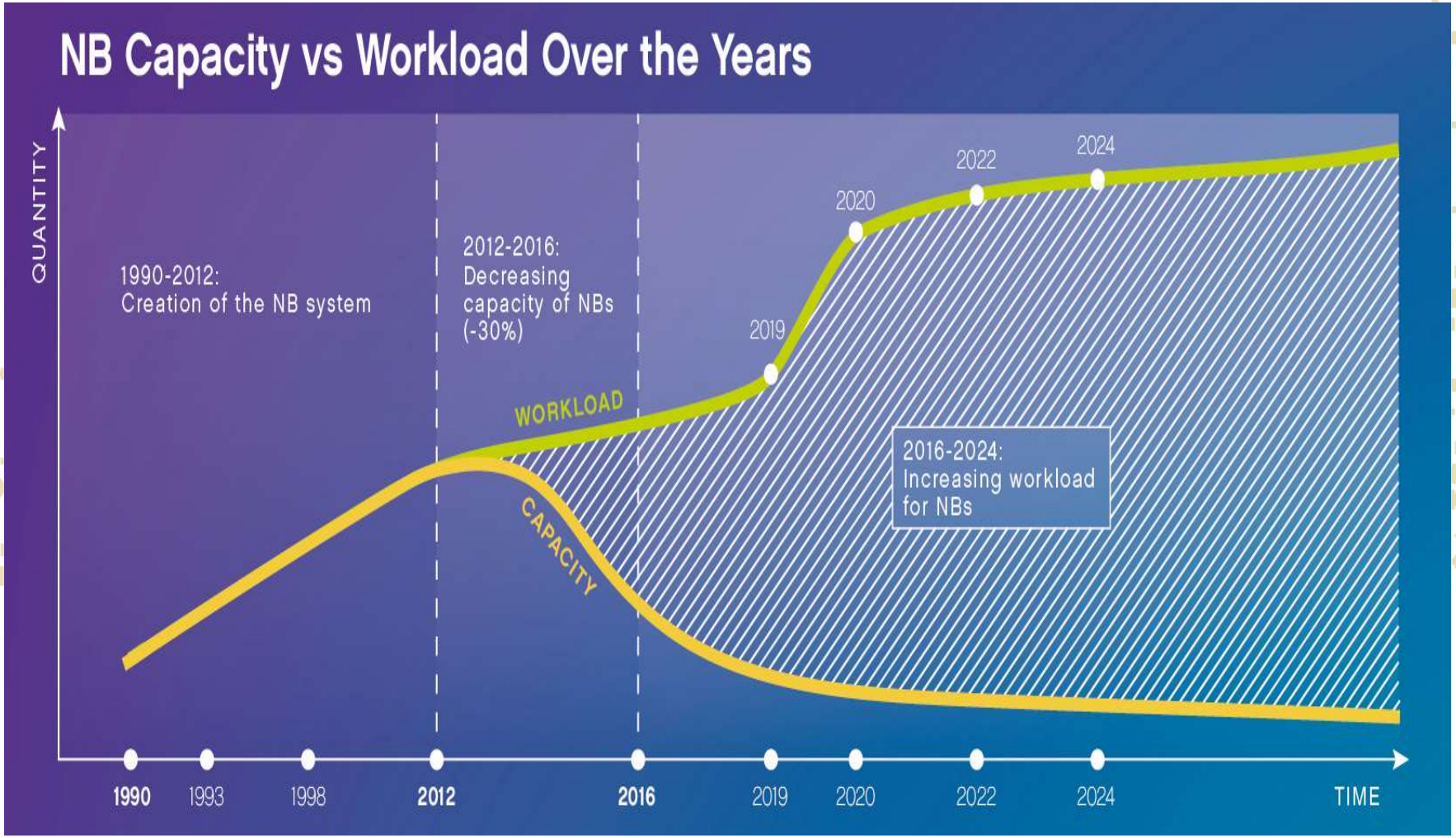
- As a general rule, clinical evidence must be:
    - Such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit(s) will be achieved and that the device is safe.
    - Sourced from performance studies that have been carried out under the responsibility of a sponsor.

- Performance evaluation plan to underpin generation and evaluation of data.
- Lifecycle approach to clinical data.

Clinical evidence details

- Download this excellent document to get you on your way.
- A lot of very practical detail about clinical evidence requirements.
- Also check Commission Staff Working Document “Current performance of COVID-19 test methods and devices and proposed performance criteria”, 16 April 2020.

Notified Body Capacity vs. Workload vs. TIME



Full chart available here: *http://www.medtecheurope.org/sites/default/files/resource_items/files/MTE_Infographic_NotifiedBodies_CrunchTime_Sept2018.pdf*

Emergency: NB bottleneck

What has to go through the bottleneck?

- Every IVD that does not have a CE certificate now and needs one under the IVDR.

Body type	Name	Country
~~NB 0086~~	~~BSI Assurance UK Ltd~~	~~United Kingdom~~
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

- Be mindful of specials under the IVDR that require you to look at scope again and require notified body and other official intervention, such as:
  - Companion diagnostics (currently often self-certified).
  - Near patient tests (treated analogous to self-testing and subject to technical documentation assessment (Section 5.1 Annex IX)).

European Commission

APPLICATIONS

- MDR: 48
  - 4 new applicants (+1 withdrawn)
  - 44 out of 49 *current** bodies – ~90%
- IVDR: 15
  - 1 new applicant
  - 14 out of 21 *current** bodies – ~67%
- Scope coverage: The entirety of MD and IVD codes

** Designated under the Directives excluding bodies from Turkey*

Health and Food Safety

Lab developed tests under IVDR

- The specific needs of target patient groups cannot be met at the appropriate level of performance by an equivalent device available on the market.
    - Must be justified permanently during life cycle of LDT.
    - Health institution must have procedure for monitoring existence and becoming available of equivalent CE marked tests.
- Internal use without need of CE mark.
    - No transfer to other legal entity.

LDTs

- CE marked test manufacturers face a struggle to be CE marked under the IVDR after 26 May 2022.
- CE marked test manufacturer problems are lab problems as this goes to availability of tests.
    - Manufacturers need to determine for each CE marked test if they will invest in IVDR remediation.
        - Lab would like to know for the tests it uses what will happen.
        - LDT as a plan B is tricky, as the LDT may not be used anymore when the equivalent CE marked test becomes available again.
- LDT regime in IVDR requires that health institutions must review and remedy all of its existing LDTs if it wants to continue using them after 26 May 2022.

LDTs and RuO supply

- RUO components and technology can still be supplied to health institutions, BUT:
    - Health institutions must have suitable production quality system (likely ISO 13485:2016 plus), which entails supplier qualification.
    - Health institution basically has to meet CE requirements “light”
        - Manufacturing and design information (article 5 (5) (e) IVDR)
        - Devices meet Annex I GSPRs (article 5 (5) (f) IVDR).
        - Class D LDTs – institution must develop detailed design dossier and technical documentation.

Component and parts

Article 20 IVDR:

1. Replacement parts that does not change performance/risk profile.
    - Item must not adversely affect the safety and performance of the device.
    - Supporting evidence shall be kept available for authorities.
        - In practice: seller must have validated non-original parts/components.
2. Replacement part that does change performance/risk or intended purpose of device.
    - Regulated as a device in its own right.

Components, parts and maintenance

- IVDR gives manufacturers much more options to prescribe requirements of preventative maintenance upon penalty of loss of CE for the instrument.
    - Annex I, point 6 IVDR – CE valid on condition of proper maintenance as specified.
    - Annex I, point 20.4.1 (s) – IFU contains information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
        - Details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;
        - Information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
        - Methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.

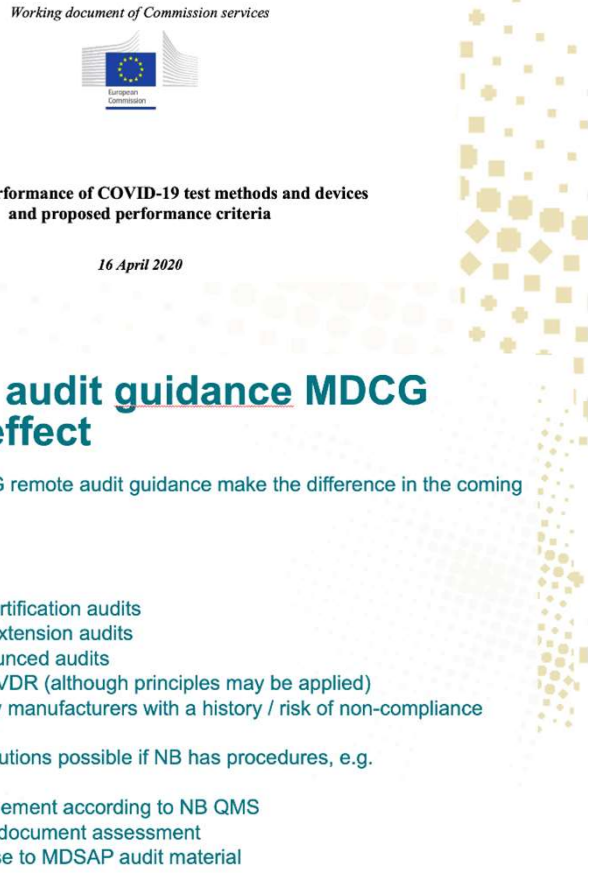
Components, parts and maintenance

- Manufacturers have more controls concerning grey market parts.
- Grey market parts should be validated or device is not covered by CE anymore.
    - Supply agreements for parts will need to account for supporting data for parts .
    - Manufactures have basis for reviewing supply agreements to require more in terms of OEM parts and training.

COVID-19 and IVDs

- No specific IVDR derogations / measures yet.
- Will the IVDR be postponed? – No, don't count on it.
- Remote audits for initial approval?
  - MDCG 2020-4 remote audit guidance for IVDD.
    - Not for IVDR but principles may apply by analogy.

For COVID-19 test cookbook see:



Working document of Commission services

European Commission

Current performance of COVID-19 test methods and devices and proposed performance criteria

16 April 2020

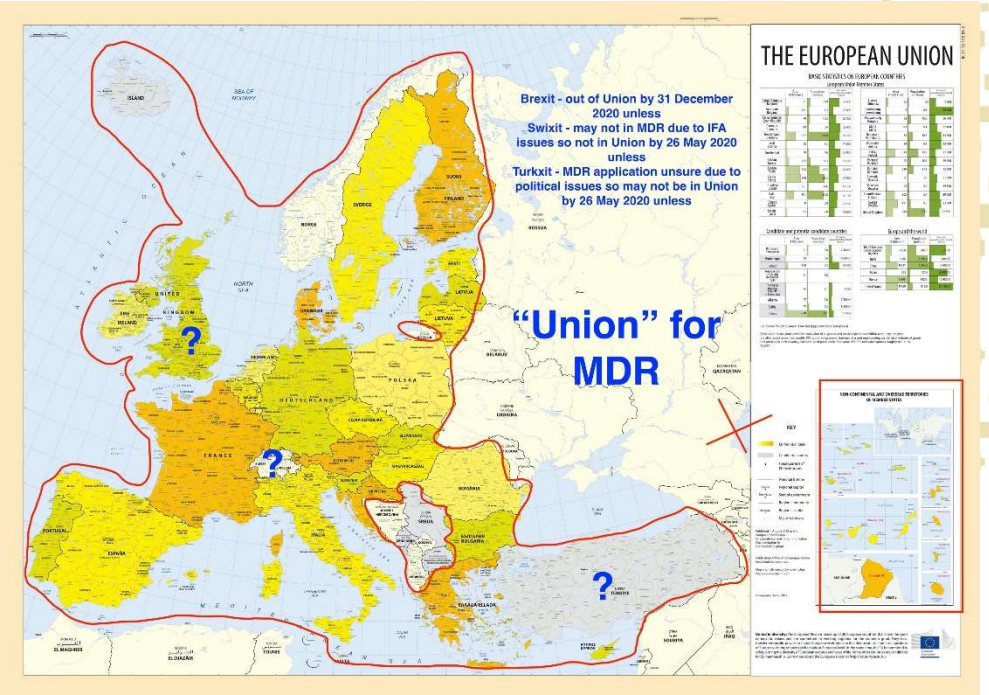
Remote audit guidance MDCG 2020-4 effect

- Will the MDCG remote audit guidance make the difference in the coming year?
- Not for
  - initial certification audits
  - scope extension audits
  - unannounced audits
  - MDR / IVDR (although principles may be applied)
  - Naughty manufacturers with a history / risk of non-compliance
- Alternative solutions possible if NB has procedures, e.g.
  - Postponement according to NB QMS
  - Off-site document assessment
  - Recourse to MDSAP audit material

Prepare for exits

- Brexit – legal deadline 31/12/20
  - May be hard, may be somewhat less hard – time is running out for anything less than a hard Brexit.
  - Watch international political developments.
- Swixit – maybe 26/05/21
  - Positive September 2020 referendum likely too late for IFA signoff.
- Turkxit – maybe 26/05/21
  - Commission: ‘this is being worked on’ but “politics.”

Find and read the EU guidance on Brexit, and what it entails: https://ec.europa.eu/health/md_sector/overview_en



Prepare for exits

- For Brexit, understand and map your supply chain that runs:
    - Into UK
        - Northern Ireland has special status
    - Through UK into Europe
- EU is better prepared than UK and will exercise all pressure possible to make the UK feel that it is on the outside as of 2021.
    - Unless there is a ‘deal’ in time for the EU’s member states to still be able to ratify nationally.

What is there left to do until DoA?

- Data data data data data, especially clinical performance

Trust data, not Lore

What is there left to do until DoA?

- Be ready to pivot based on new EU guidance becoming available.
    - CAMD still seems to be working on things.
- Get the economic operator stuff right.
    - PRRC guidance less than comprehensive
    - Industry struggles to understand degree of independence required for AR and PRRC.
    - New Market Surveillance Regulation (Regulation (EU) 1020/2019.
- Keep your friends (crucial suppliers) close and your notified body closer.

What is there left to do until DoA?

- Be ready to implement Eudamed interfacing and process, have SRN (if OUS Union then have AR with SRN first) and prepare for UDI.
    - Eudamed Actor module opens for voluntary use as of 1 December
    - Staged release of modules in four batches (March 2020, November 2020, May 2021, May 2022).
- Be intelligent with long term commitments (e.g. tenders)
    - Can you guarantee supply of every device over the next five years?
    - Do you have a plan B?

What is there left to do until DoA? Plan B

- Have plan B for scenarios:
    - Hard Brexit
    - Switzerland and Turkey not being Union under MDR
    - Notified body calamities
        - NB shuts down/certs invalid as a result of Brexit, Swiss or Turkish dependency.
        - NB misses MDR deadline for IVDD or IVDR (re)certification.
    - Other problems with organisation/certification status that lead to disruptions.
        - Understand supply chain and concept of placing on the market.
        - Have supply chain scenarios.
        - Understand national exemption regimes for essential devices.

Thanks for your attention!

AXON
science based lawyers

Erik Vollebregt
Axon Lawyers
Piet Heinkade 183
1019 HC Amsterdam
T +31 88 650 6500
M +31 6 47 180 683

E erik.vollebregt@axonlawyers.com
@meddevlegal
B http://medicaldeviceslegal.com

READ MY BLOG:
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Bonus slides General Data Protection Regulation

Interplay IVDR and GDPR

Performance evaluation under IVDR

- IVDR requires more in terms of performance evaluation and requires that it happens in conformity with EU data protection rules

- Performance evaluation plan (Annex XIII, 1.1)

    - Demonstration of the scientific validity and the analytical and clinical performance (Annex XIII, 1.2)
    - Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources (Annex XIII, 1.2.3):
        — clinical performance studies;
        — scientific peer-reviewed literature;
        — published experience gained by routine diagnostic testing.
    - The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and /or previous experience gained by routine diagnostic testing.
    - Clinical performance studies must be performed unless due justification is provided for relying on other sources of clinical performance data

Performance evaluation under IVDR

- Annex XIII, section 2 contains detailed requirements for clinical performance studies and defines exceptions for studies with left-over samples and requirements regarding relying on clinical evidence based on left-over sample derived data
    - E.g. for clinical performance study plan (CPSP)
    - Use of of left-over samples versus interventional clinical performance studies may need to be justified in CPSP (Annex XIII, 2.3.2)

IVDR on left-over samples studies

- Studies with left-over samples are generally ‘normal’ performance studies under the IVDR, unless they are are studies (article 58 (1)):

  a) in which surgically invasive sample-taking is done only for the purpose of the performance study;
  b) that is an interventional clinical performance study as defined in point (46) of Article 2; or
  c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies

  - In cases a), b) and c) additional requirements apply

- All performance studies are subject to scientific and ethical review (article 58 (3) IVDR), also in the case of performance studies for companion diagnostics (article 58 (2) IVDR)

IVDR on left-over samples studies

- So… studies with left-over samples are generally ‘normal’ performance studies under the IVDR
    - So no notification to the national authorities as IVDR regulated study
    - BUT: you may need to notify locally for ethical approval
        - Recital 73: “It is necessary to clarify that performance studies using left-over specimens need not be authorized. Nevertheless, the general requirements and other additional requirements with regard to data protection and the requirements applicable to procedures that are performed in accordance with national law such as ethical review should continue to apply to all performance studies, including when using left-over specimens.”
        - also in the case of performance studies for companion diagnostics (article 58 (2) IVDR)

IVDR and GDPR – why?

- Article 57 (3) IVDR:

bsi. „making excellence a habit"

"Performance studies shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are scientifically valid, reliable and robust.

Performance studies, including performance studies that use left-over samples, shall be conducted in accordance with applicable law on data protection. "

(Clinical) performance studies – informed consent

- To be valid, consent to the processing of personal data must:
  - be *freely given, specific, informed and unambiguous*
  - be *explicit* for data concerning health
  - be a *clear affirmative action*
    - *Silence, pre-ticked boxes or inactivity should … not constitute consent*
  - cover *all processing activities* carried out for the same purpose
- Consent is not *freely given*, where there is a *clear imbalance* between the data subject and the controller (Recital 43 GDPR)
- Consent is presumed not to be *freely given*, if:
  - it does not allow separate consent to be given to different data processing operations despite it is appropriate in the individual case
  - the data subject had no genuine and free choice
  - the data subject was unable to withdraw or refuse consent without detriment

(Clinical) performance studies– informed consent

- Evolution of the ICF
    - Address foreseeable use, including secondary use that is not scientific research (‘informed’)
        - e.g. incorporation in other datasets, provision to third parties
        - Geographic locations / international transfers
    - Separate data protection consent from trial consent
    - Address imbalance problem (‘freely’)

(Clinical) performance studies - withdrawal

- Any study participant has the right to withdraw consent at any time without any explanation or any consequences, and the GDPR once more emphasizes this.

- Right to be forgotten / effect of withdrawal?
  - Article 58 (6) last para IVDR: “Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.”
  - right to be forgotten (article 17 GDPR): erasure of data does not apply when processing of data is necessary for
    - “ … scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; …”
- In other words, in case a study participant withdraws consent, processing of the data collected until that point in time is still possible if such is needed for the objective of the study.

Right to be forgotten = obligation to destroy?

- Not clarified under IVDR / GDPR whether the right to be forgotten implies that samples have to be destroyed, cannot be used for new research or have be be anonymized
- The effect of withdrawal depends on MS legislation and (inter)national guidelines
- E.g. eTRIKS code on Practice on Secondary Use of Medical Data in Scientific Research Projects (Rule 28): Destruction of all samples and derivatives
  - *if* the samples of the donor can still be identified and
  - *unless* applicable law requires maintenance of the data
- Equally applicable to non-research uses?

- NB. Differentiate between *withdrawal from participation in the performance test* and *withdrawal for using secondary data*. When data is anonymized, it is no longer 'you' who participates.

Clinical or performance research – secondary processing

- GDPR recognises that "secondary" *processing for scientific research purposes should be considered to be compatible lawful processing operations* (Recital 50)
  - Value of research & registries are recognised, but subject to national law (Recital 157)
  - "Broad consent" is not normally not allowed, but it may be possible to obtain consent for *areas* of scientific research (Recital 33)
    - data subject should have the opportunity to consent only *to certain areas of research or parts of research projects*
  - Processing of data concerning health is prohibited without explicit consent, Member State (or the EC) law may allow processing for research purposes with *appropriate safeguards* (Article 89(1))
    - Technical & organizational measures to ensure data minimization. This MAY be pseudonymization.
    - Once research can be conducted without personal data, derogation should cease.
- Member State law may derogate from certain rights of data subjects *in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes* (Article 89(2))

Scientific research = performance evaluation?

- a defined and methodologically sound procedure based on critical evaluation of (Article 56 (2) (a) – (c) IVDR)
  - scientific validity
  - analytical performance
  - clinical performance

- Is this scientific research?
  - Is preparing a market access submission scientific research?
  - Is the activity of performance evaluation as such scientific research?

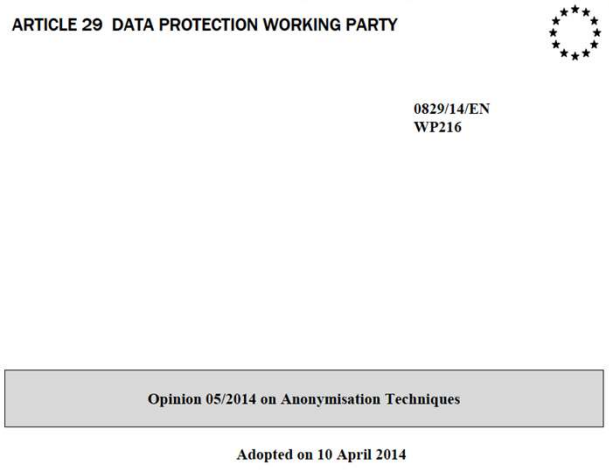
  - If not, scientific research exemption provisions in GDPR do not apply

Pseudonymization and anonymization: personal identifiers

- The GDPR definition of what is considered identifiable is very broad, and not just looking at a name or date of birth:
    - “an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person”
- GDPR provides that pseudonymization is a reversible security measure, but not a de-identification measure (see article 25 re privacy by design recitals 26 and 28 and recital 156 in relation to secondary processing for research)

Pseudonymization and anonymization: personal identifiers

- Removal of direct identifiers is not anonymization:
    - “Personal data which have undergone pseudonymization, which could be attributed to a natural person by the use of additional information should be considered to be information on an identifiable natural person.” (recital 26 GDPR)
- See Article 29WP opinion WP216 on anonymization techniques


ARTICLE 29 DATA PROTECTION WORKING PARTY

0829/14/EN
WP216

Opinion 05/2014 on Anonymisation Techniques

Adopted on 10 April 2014

MDR and GDPR: overlap of risks and different approaches

MDR / IVDR

- Security by design aimed to safeguard safety and performance (Safety, Reliability and Availability (SRA) for cyber physical systems)

GDPR

- Security by design and default aimed at data integrity (Confidentiality–Integrity–Availability (CIA) for corporate processes)

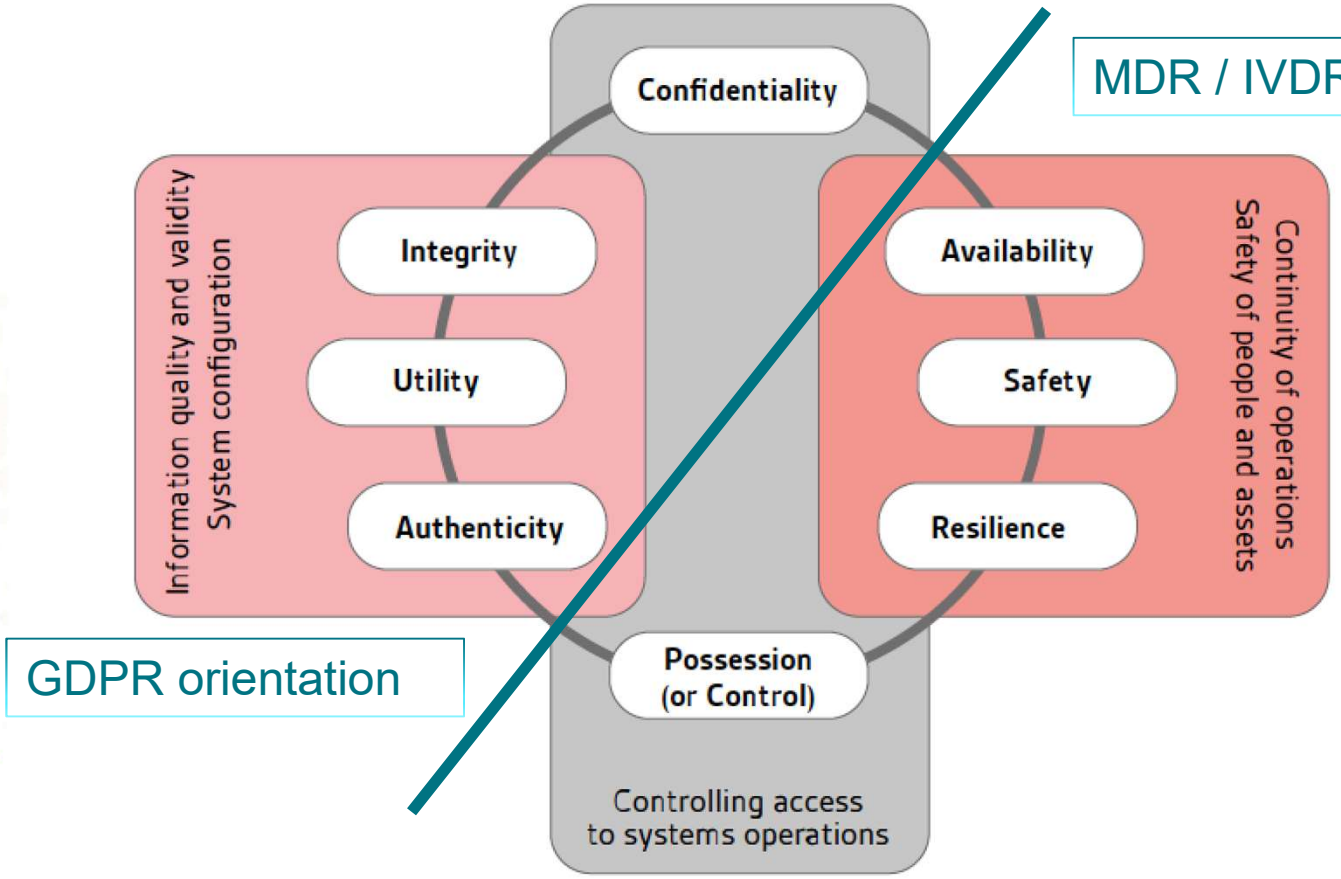
Map security risks under GDPR that are also (partially) safety and performance risks under MDR / IVDR

- Those risks are subject to AFAP reduction by means of design insofar as they concern the device (GSPR 2 and EN ISO 14971:2012 ZABC annexes)

Overlap of risks and different approaches - nice model

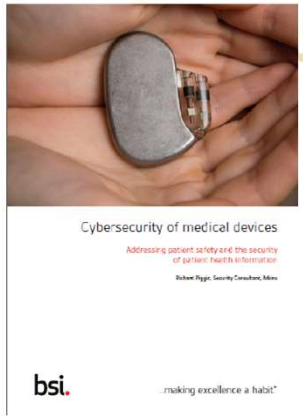
Figure 4 – Cyber physical assurance framework based on the Parkerian Hexad*

Courtesy of Hugh Boyes – Cybersecurity and Cyber-Resilient Supply Chains. Technology Innovation Management Review, 2015



MDR / IVDR orientation

GDPR orientation



Secondary processing – Member State legislation

- Individual MS may require extra safeguarding measures for secondary use of health data and/or samples (Article 9 (2) (j) GDPR) or special data in general (Article 9 (4) GDPR)
- The secondary uses of such health data may cover general research/scientific purpose, epidemiology, statistics or other uses
  - Be aware: national legislation may also prohibit certain secondary uses!

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SI	SK	SE	UK
Anony-mised data	√	√	√		√		√	√		√	√	√		√		√	√	√	√		√	√	√	√	√	√	√		√

	AT	BE	BG	CY	CZ	DE	DK	EE	EL	ES	FI	FR	HR	HU	IE	IT	LT	LU	LV	MT	NL	NO	PL	PT	RO	SI	SK	SE	UK
Patient consent		√						√				√					√					√						√	√

Source: Milieu Ltd – time.lex (Brussels) Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services, July 2014 / 8

- Extra safeguarding measures may also include pre-authorization

Thanks for your attention!

AXON
science based lawyers

Erik Vollebregt
Axon Lawyers
Piet Heinkade 183
1019 HC Amsterdam
T +31 88 650 6500
M +31 6 47 180 683

E erik.vollebregt@axonlawyers.com
@meddevlegal
B http://medicaldeviceslegal.com

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http://medicaldeviceslegal.com