European IVDR – where are we?

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Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.

405 days

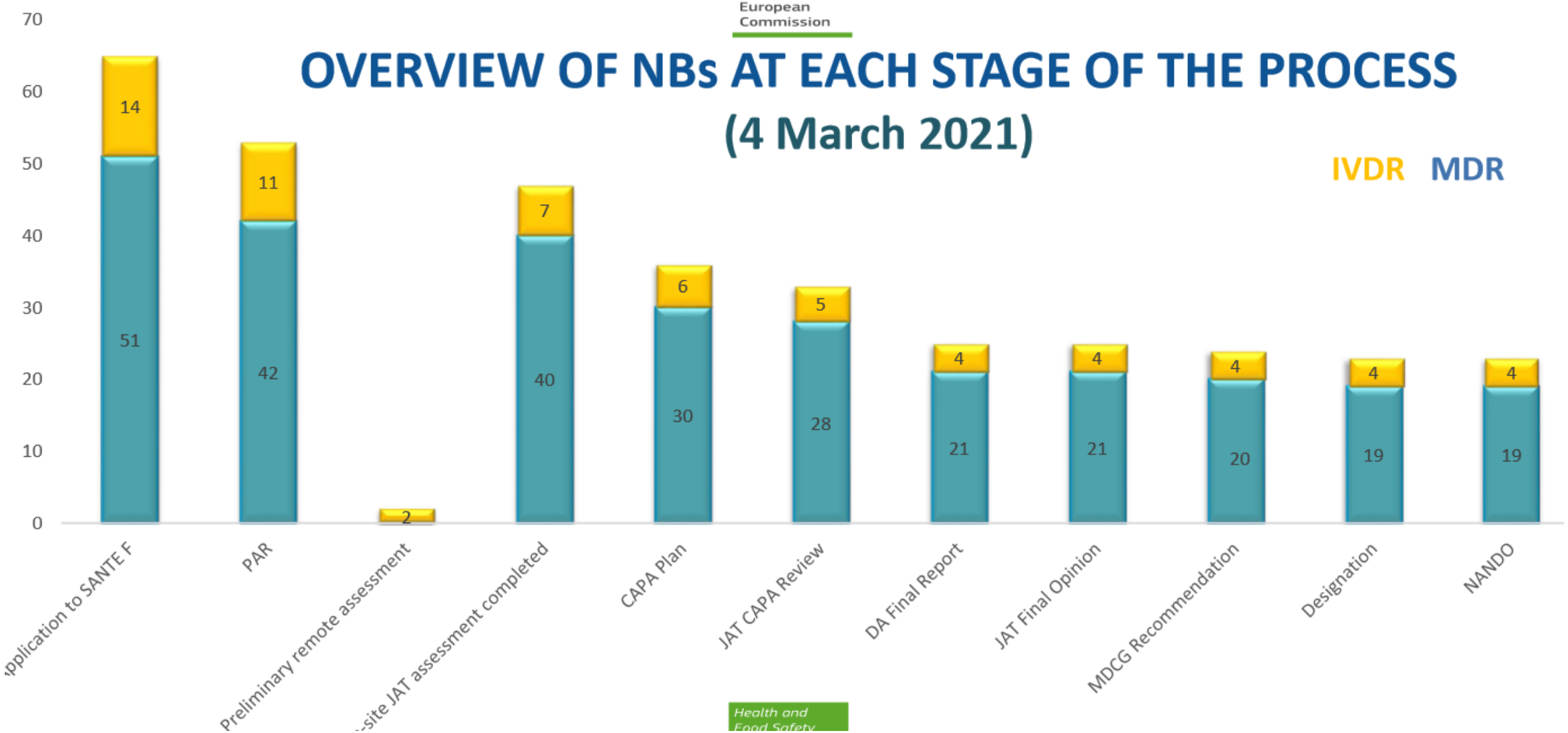
(1 year, 1 month, and 10 days)

Agenda

- State of play – March 2021
- Common Specifications, EU Ref labs, Expert panel
- MDCG guidance documents, and Eudamed
- NBCG IVD Working groups
- Last thoughts

European Commission

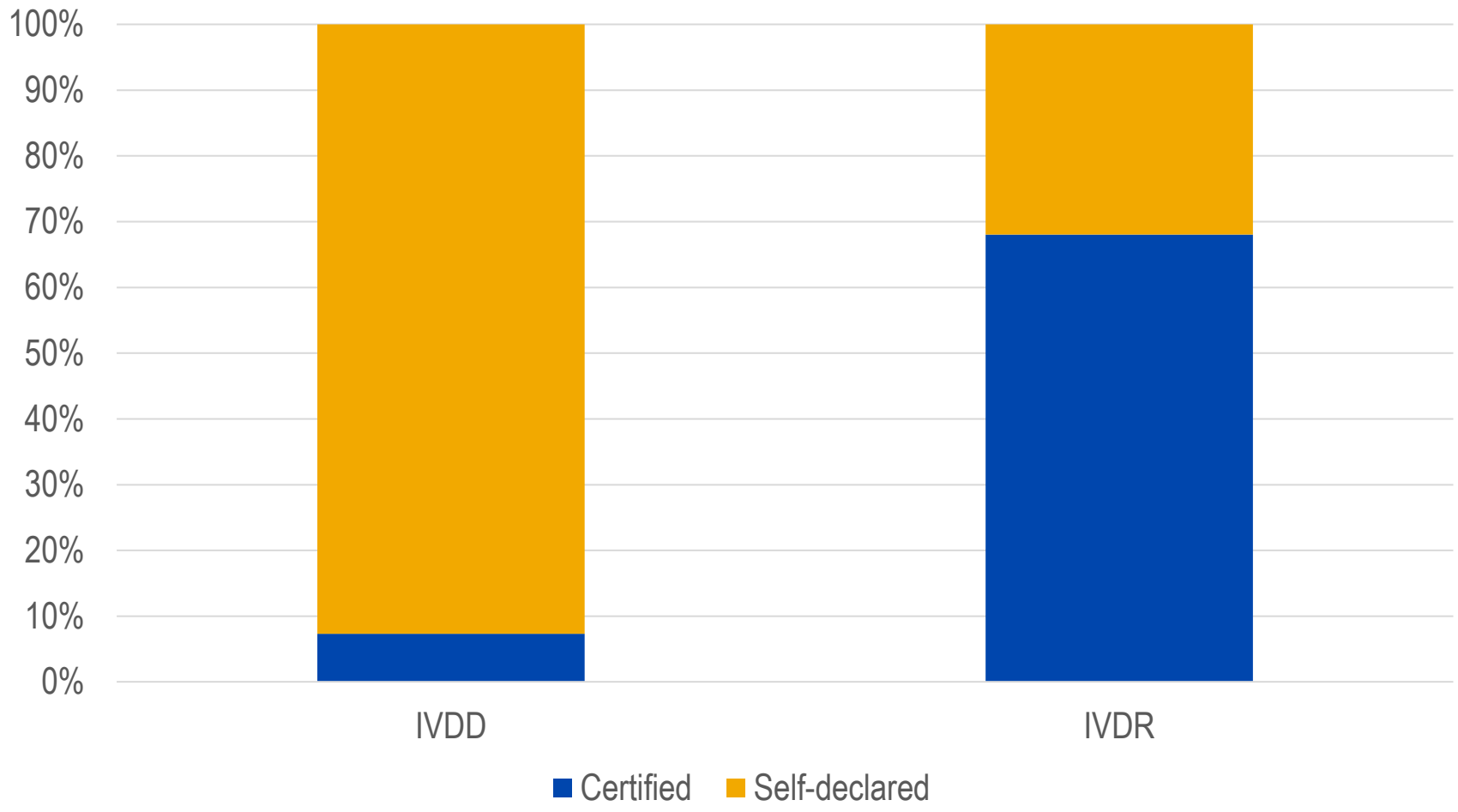
OVERVIEW OF NBs AT EACH STAGE OF THE PROCESS (4 March 2021)



Designated Notified Bodies

Body type	Name
NB 2797	BSI Group The Netherlands B.V.
NB 0124	DEKRA Certification GmbH
NB 0197	TÜV Rheinland LGA Products GmbH
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen

The need for Notified bodies



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Common Specifications Implementing Acts

To be adopted by Q2 2021

Drafts available or in preparation

- Definitions and Terms
- HIV
- HTLV I & II
- Hepatitis B, C & D
- NAT
- Blood Group Antigens
- vCJD
- Kidd & Duffy (mature draft)
- Chagas & Syphilis (draft with few open questions)?
- Cytomegalovirus (CMV) and Epstein-Barr Virus (EBV)

SARS-CoV-2 (draft available for stakeholder review)

Adopted by Q4 2021 or later

To be drafted/requiring lead(s)

Batch 2) Hepatitis E (to be grouped with Hepatitis B, C & D)

Batch 3) Plasmodium (Malaria) and Toxoplasma

Batch 4) Highly virulent pandemic influenza virus

Batch 5) SARS & MERS Coronavirus ?

Batch 6) Ebola virus, Lassa virus,Crimean-Congo haemorrhagic fever (CCHF) virus and Marburg virus ?

Commission Implementing Decision (EU) 2019/1244

- COMMISSION IMPLEMENTING DECISION (EU) 2019/1244 of 1 July 2019 amending Decision 2002/364/EC as regards requirements for:

  - HIV and HCV antigen and antibody combined tests
    i. Revision of Table 1 and Table 5 - requirements for sensitivity and specificity
  - Nucleic acid amplification techniques
    i. Reference materials calibration requirements
  - Qualitative HIV NAT assays:
    i. Detect both HIV-1 and HIV-2
    ii. Use of two independent target regions for HIV-1

- Revised CTS are applicable from 02/07/20

EU Reference Labs – Implementing acts

- Three Implementing Acts expected*

IVDR Reference	Description	Expected availability
Article 100(8)(a)	Tasks of the EURL	Q1 2021
Article 100(8)(b)	Fees of the EURL	Q1 2021
recital 94 Articles 48(6), 100(1) and (3),113(d)	Designation of EURL	Q3-Q4 2021

- Current status: survey to establish required capacity is ongoing. Stakeholders consulted: Competent Authorities, Notified Bodies, MedTech Europe

* Source: MDR/IVDR Implementation Rolling Plan Dec. 2020
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_rolling-plan_en.pdf

Expert Panels Appointed

- IVDR Art 48 6./Annex IX 4.9

- **Consultation of Expert Panel**

  - For class D devices
    - where no CS are available and
    - where it is also the first certification for that type of device
    - the NB shall consult the relevant experts (IVDR, article 48.6)

  - NB to forward the **Performance Evaluation Report** of manufacturer to Expert Panel **within 5 days** from receipt

  - Experts to provide their view **within 60 days**

- Expert Panels were appointed Q4 2020, however not yet operational
- Full list of experts and Rs&Rs available at: https://ec.europa.eu/health/md_expertpanels/overview_en

Expert Panels Appointed

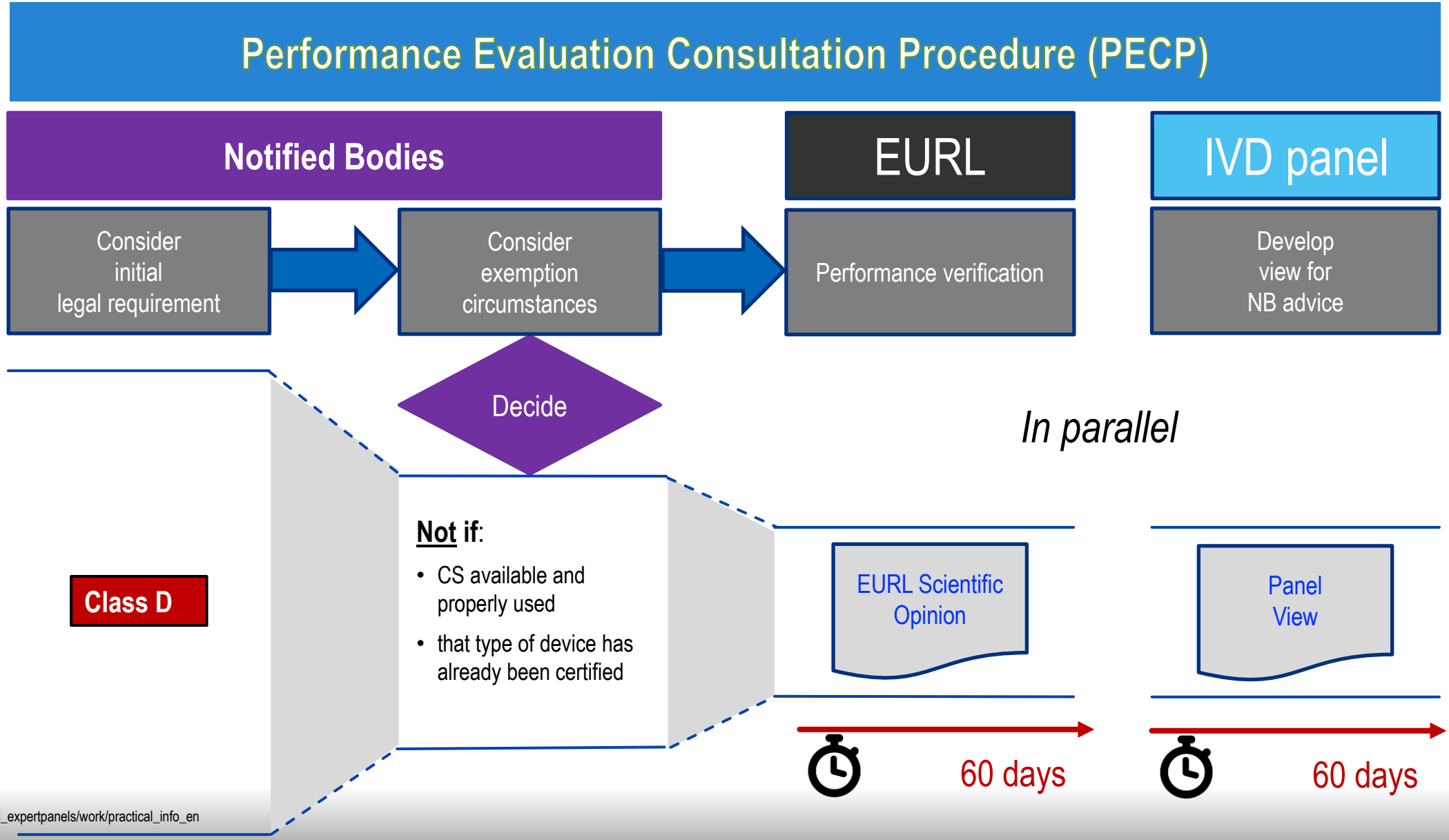
To be implemented later

Medical devices Regulation (MDR) *Recital 83*	IVD Regulation (IVDR) *Recital 53* *Article 50.3*
ad hoc advice	
Expertise & assistance in relation to the **implementation** of the MDR, including advice on safety & performance of specific high risk devices	Advice on safety & performance of specific high-risk devices

Implementation in progress

routine advice in the context of regulatory procedures	
Review clinical evaluation assessment reports of notified bodies: *'CECP' = clinical evaluation consultation procedure*	Review performance evaluation reports: *PECP = performance evaluation consultation procedure*

Expert Panels Appointed



https://ec.europa.eu/health/md_expertpanels/work/practical_info_en

MDCG current and future guidance

- MDCG Endorsed Guidelines are available at:

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en

- Legally non-binding guidance documents, however application of MDCG guidance document encouraged
- Ongoing MDCG guidelines are also publicly available
- > 50 Guidelines and forms were endorsed as of January 2021; several additional guidance documents are still being worked on, including IVD specific documents

MDCG 2020-15 EUDAMED and Single Registration Number availability

- Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States

  i. EUDAMED Actor registration module available since 1 December 2020
  ii. Actor registration strongly encouraged, but voluntary
  iii. Use of Eudamed cannot be mandatory until it is fully functional*
  iv. Current forecast is that this will not happen until May 2022
  v. Registration obligation in EUDAMED in lieu of national registration

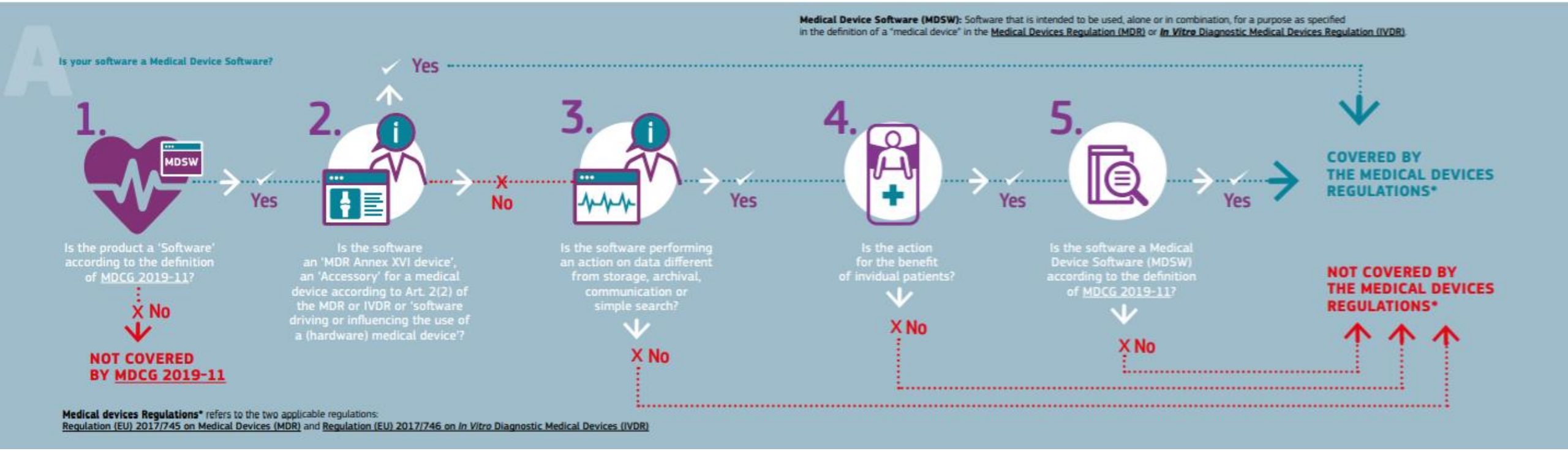
* Fully functional= 'Minimum Viable Product (MVP)

Expected Guidance documents

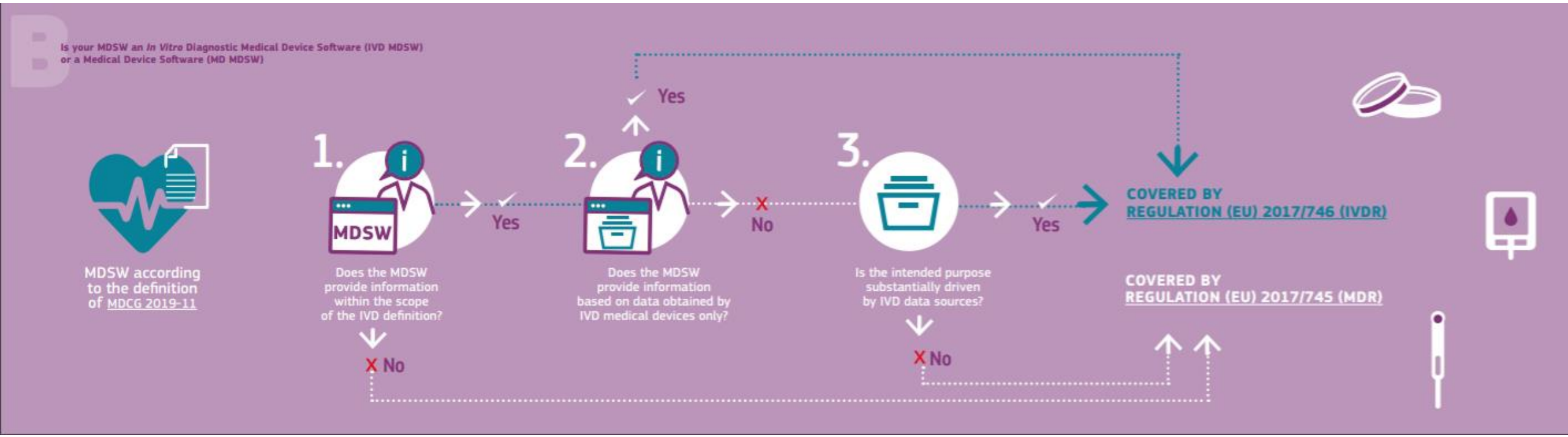
Topic	Current Status	Expected availability
Performance Evaluation	Comments received as part of stakeholder consultation	2021
SSP Template and guidance		2021
Explanatory note on NB codes	Ongoing/First draft received for comments on 05/02/21	Q2 2021
PMS/Vigilance	Multiple guidance documents being prepared	2021
Batch verification on class D IVDs	Ongoing	Q2 2021

Complete list of ongoing MDCG Guidance documents is available at:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_ongoing_guidancedocs_en.pdf

Other guidance documents – is your software a medical device?



Other guidance documents – is your software a medical device?



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NBCG WG Updates: Companion Diagnostics

Goal

- Develop an approach for assessment of Companion Diagnostics under IVDR and interaction with EMA or, i.a., national medicinal product authorities.
- Joint work between NB and EMA

Current Status

- NB/EMA Consultation procedure drafted
- Collect IFU examples of existing CDx device and provide them to EMA for evaluation

Next steps

- Get buy-in of the Commission on the consultation process
- Challenge the consultation procedure by running a pilot test
- Align on required IFU/SSP contents

NBCG WG Updates: Clinical Evidence and Performance evaluation

Goal

Harmonize interpretation of requirements for clinical evidence for IVD devices under IVDR and development of guidance

Current Status

Reached alignment on topics such as intended purpose/use
Provided feedback to draft MDCG guidance on PE

Next steps

Further actions depending on final version of MDCG guidance

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Lessons learnt from MDR implementation

Balance between resources for IVDD vs IVDR assessments

It is necessary to ensure that

- IVDD EC certificate extensions:

  - Apply early!
  - Late applications will be expensive, may not be completed in time

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

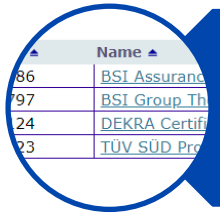
No. V1 88888 01234 Rev. 01

Manufacturer: **Testkunde GmbH**
Testkunde Name2

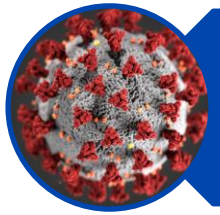
What keeps me awake at night

Large product lists out of nowhere

Poor TDs (30-40%)



NB designations



COVID 19 development

? QUESTIONS ?

спасибо
GRACIAS 谢谢
THANK YOU
ありがとうございました MERCI
DANKE धन्यवाद
شُكراً OBRIGADO
Gracie
감사합니다

Stay informed and Updated

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