MDR Implementation – A Notified Body Perspective

CORE-MD

25 March 2024

Agenda

1. Interesting Newspaper Headlines
2. MDR Expectations
3. MDR Implementation
4. Transparency, Predictability
5. Questions & Answers

MP attacks 'dodgy auditing' and conflicts of interest

16 October 2008

Meacher later told *Accountancy Age* he thought there were some issues with conflicts of interest at auditors. He claimed that a number of firms 'have commercial relationships with those they audit' and claimed there was 'plenty of evidence that Chinese walls' within firms 'are breached'.

He also criticised reports that are overly complicated and lack transparency. 'One condition of having government money must be that the role of their auditors must be rigorously independent,' said Meacher.

Auditors of the major banks being taken into state ownership have made millions in non-audit fees. RBS paid Deloitte £17m in audit fees and £14.2m in non-audit fees in 2007.

Lloyds TSB's audit fee paid to PricewaterhouseCoopers was £12m, with only £800,000 paid in non-audit fees. The accounts said the non-audit fees related mostly to corporate finance work.

HBOS, audited by KPMG, paid £8m for its audit and £2.4m on non-audit work, including tax, IT, corporate finance and other miscellaneous services.

LEHMAN BROTHERS

northern rock

icesave
PART OF LANDSBANKI, REYKJAVIK, ICELAND

Merrill Lynch

Monitoring of safety practices and ethics needed

09 June 2010

BP says the accident was caused by the failure of eight different safety systems that were meant to prevent this kind of incident:

Dodgy cement

Valve failure

Pressure test misinterpreted

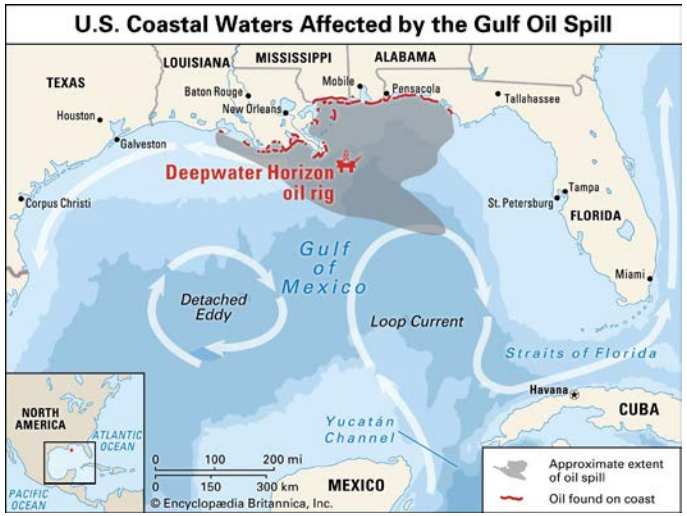
Leak not spotted soon enough

Valve failure no. 2

Overwhelmed separator

No gas alarm

No battery for Blow Out Preventor



Flawed analysis, failed oversight –

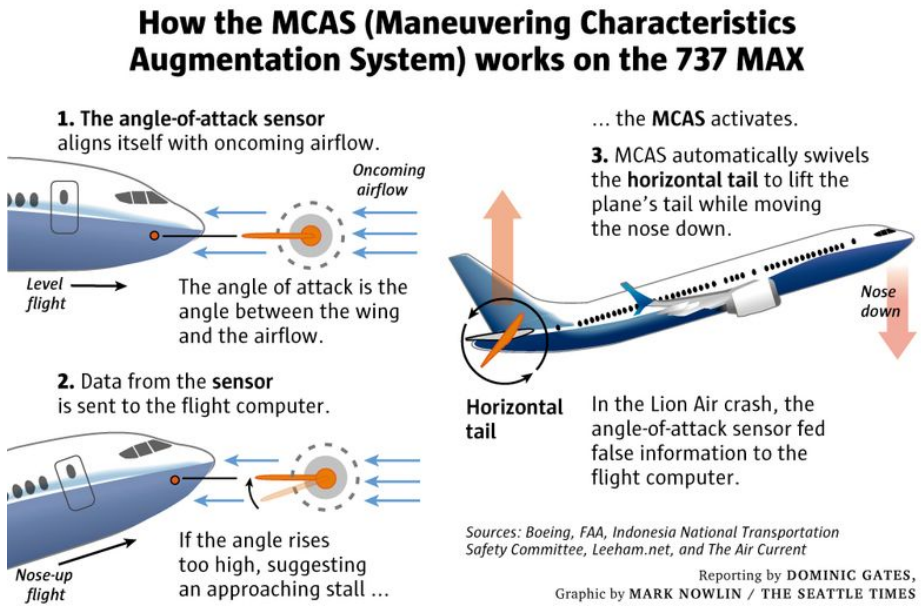
21 March 2019

Delegated to Boeing

The FAA, citing lack of funding and resources, has over the years delegated increasing authority to Boeing to take on more of the work of certifying the safety of its own airplanes.

Early on in certification of the 737 MAX, the FAA safety engineering team divided up the technical assessments that would be delegated to Boeing versus those they considered more critical and would be retained within the FAA.

"There wasn't a complete and proper review of the documents," the former engineer added. "Review was rushed to reach certain certification dates."



Production pause over safety scandal

26 December 2023

oyota-owned carmaker Daihatsu has closed all four of its plants until the end of January, after admitting it had falsified safety tests.

Daihatsu admitted that it had been manipulating safety tests on 64 makes for three decades. Its headquarters in Osaka, Japan was the last to close, on 25 December. The scandal puts in jeopardy 9,000 workers in the country and could affect global car giant Toyota's reputation. Of the 64 models involved in the scandal, 24 are sold with Toyota branding. The closure of its Osaka plant follows closures in its production lines in Oita, Shiga and Kyoto prefectures. Daihatsu said on Wednesday that it had stopped shipments of all its vehicles after its latest admission, which followed a transport ministry investigation.

It seems test results were falsified because of pressure to keep production rolling. The company said it would work with its main suppliers to address the fallout from the scandal, adding that it may also help its smaller subcontractors that do not receive compensation to access support funds from Japan's transport ministry. It also said that during the time plants are idle it would compensate 423 domestic suppliers with which it has direct business relations. Established 1907, Daihatsu sells around 1.1 million cars per year, which make up around 10% of Toyota's 10 million vehicle sales per year.

Slowing down Innovation

22 June 2023

Titan was never certified or classed.

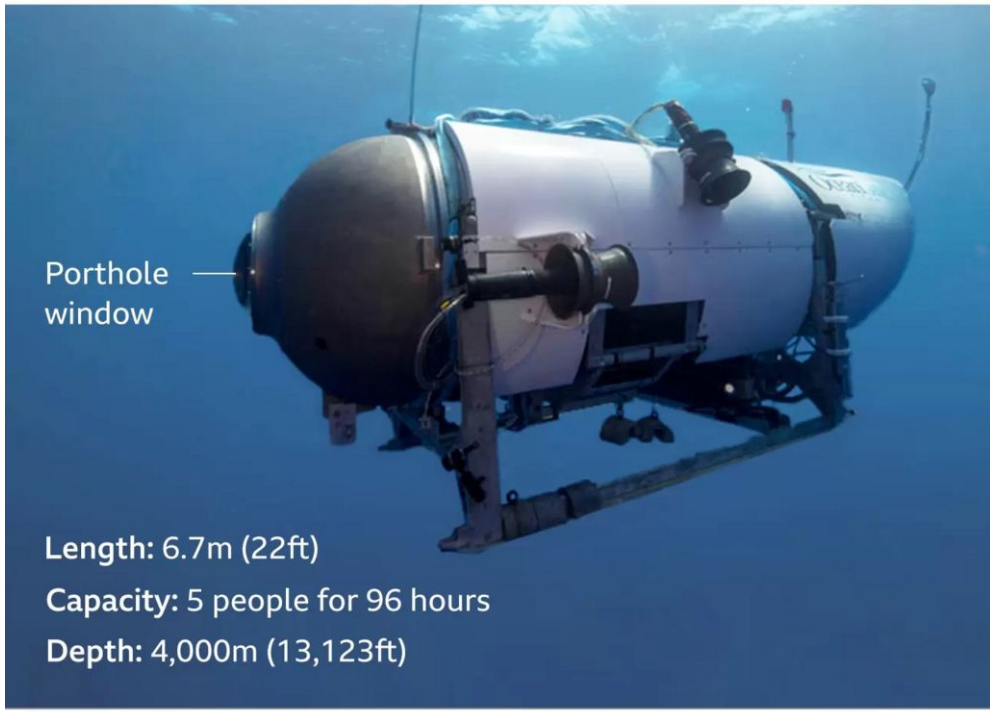
It said the way that Titan had been designed fell outside the accepted system - but it "does not mean that OceanGate does not meet standards where they apply."

It added that the classification agencies "slowed down innovation… bringing an outside entity up to speed on every innovation before it is put into real-world testing is anathema to rapid innovation".

A CBS reporter who went on the Titan in 2022 quoted a waiver people signed before boarding as stating it was "an experimental submersible vessel that has not been approved or certified by any regulatory body which could result in physical injury, emotional trauma or death."

Any sub that dives over 4,000m is a one-off vehicle - not something mass-produced - and requires innovation and novel design to survive at these depths.

Titan submersible



Source: OceanGate Expeditions BBC

MDR Expectations

Meeting of Medical Device Competent Authorities and Notified Bodies – Brussels, 27 October 2016

Keynote speech by Director Carlo Pettinelli
at the meeting with Medical Device Competent Authorities and Notified Bodies
Brussels, 27 October 2016

Ladies and Gentlemen,

I would like first of all to thank all of you for being here today and for accepting the Commission's invitation. This is the first official meeting with all Competent Authorities and Notified Bodies following the agreement on the new texts in June.

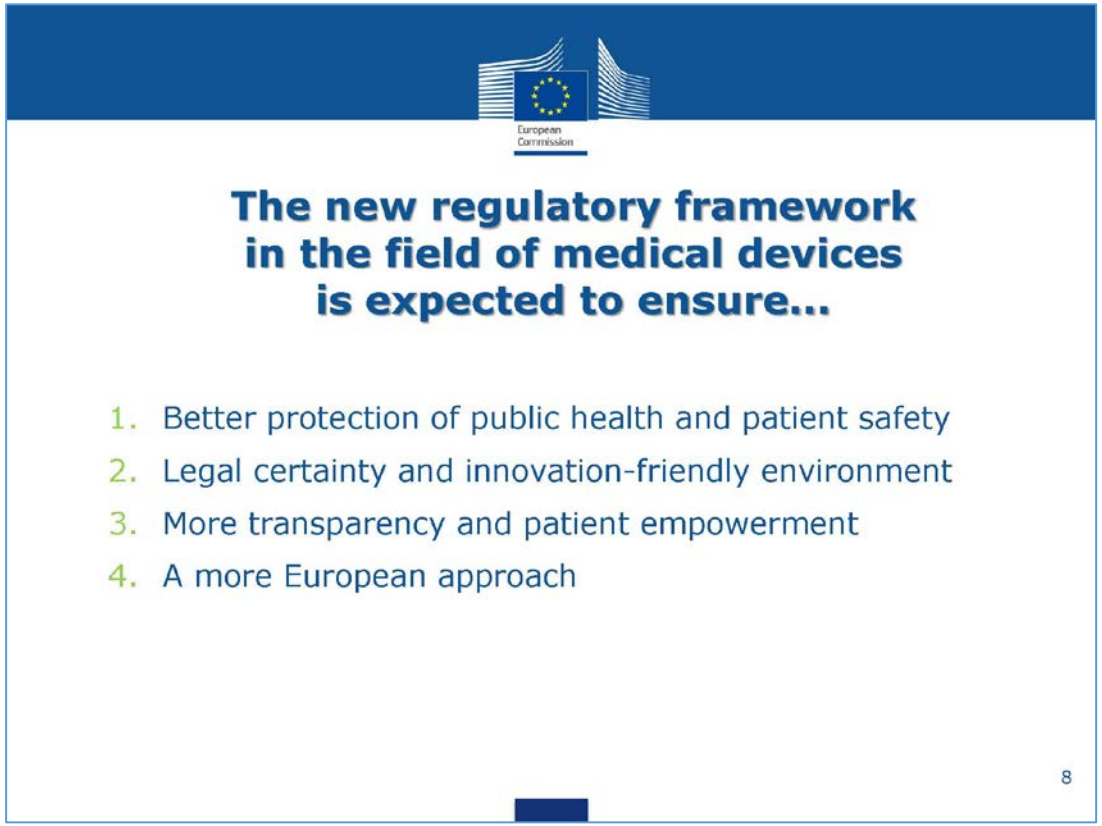
And I was particularly keen to ensure that the first official presentation of the European Commission on the new Regulations took place today, before any other external occasion. This is because the Commission is aware that smooth implementation of the new system relies on three basic actors: the European Commission, the Member States and the Notified Bodies, Good and continuous cooperation among these three actors is the **real key to guarantee a successful implementation**.

Response to 'scandals' to restore confidence in system

Keep pace with scientific and technical developments

Overcome divergence in interpretation and application

MDR Expectations



MDR Expectations

1. Better protection of public health and patient safety

- Strict pre-market control of high-risk devices with involvement of experts
- Inclusion of certain aesthetic devices
- Reinforced designation and oversight of Notified Bodies
- Reinforced rules on clinical evaluation and clinical investigation
- Strict rules for substance-based devices
- Strict rules for use of hazardous substances
- Introduction of UDI

2. Legal certainty and innovation-friendly environment

- Use of 'regulation' as a regulatory tool
- Clarification of scope for both MD and IVDs
- Stronger role for the Commission on the regulatory status of products
- Clarification of regime applicable to devices manufactured and used in the same healthcare institution
- Clarification of responsibilities of economic operators
- New rules for software / apps

3. More transparency and patient empowerment

- Establishment of EU database on medical devices (EUDAMED) with a large part to be made publicly available
- Introduction of an implant card to be provided to patients
- Summary of safety and performance for all Class III and implantable devices available in EUDAMED
- New obligations for manufacturers and authorised representatives aimed at protecting consumers / patients

4. More European approach

- Registration of devices and economic operators at the EU level
- Improved coordination between Member States in the fields of vigilance and market surveillance
- Confirmation and strengthening of the EU joint assessment procedure for notified bodies
- Introduction of a coordinated assessment of clinical investigations conducted in more than one Member State

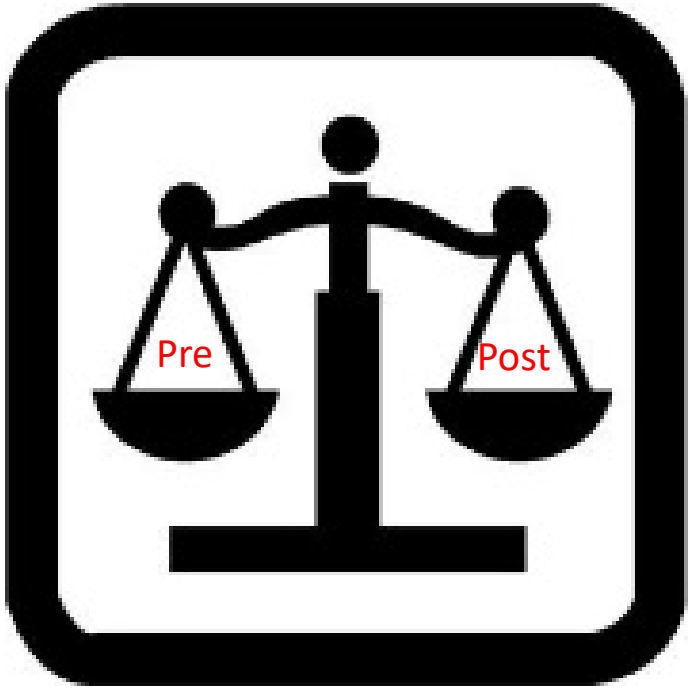
MDR Expectations

Inclusion of products with no medical purpose

3rd party review of reusable surgical instruments, custom made implants …

Upclassification of meshes, IVF media, spinal implants, joint replacements, software …

Pre-market control with expert panels



EUDAMED

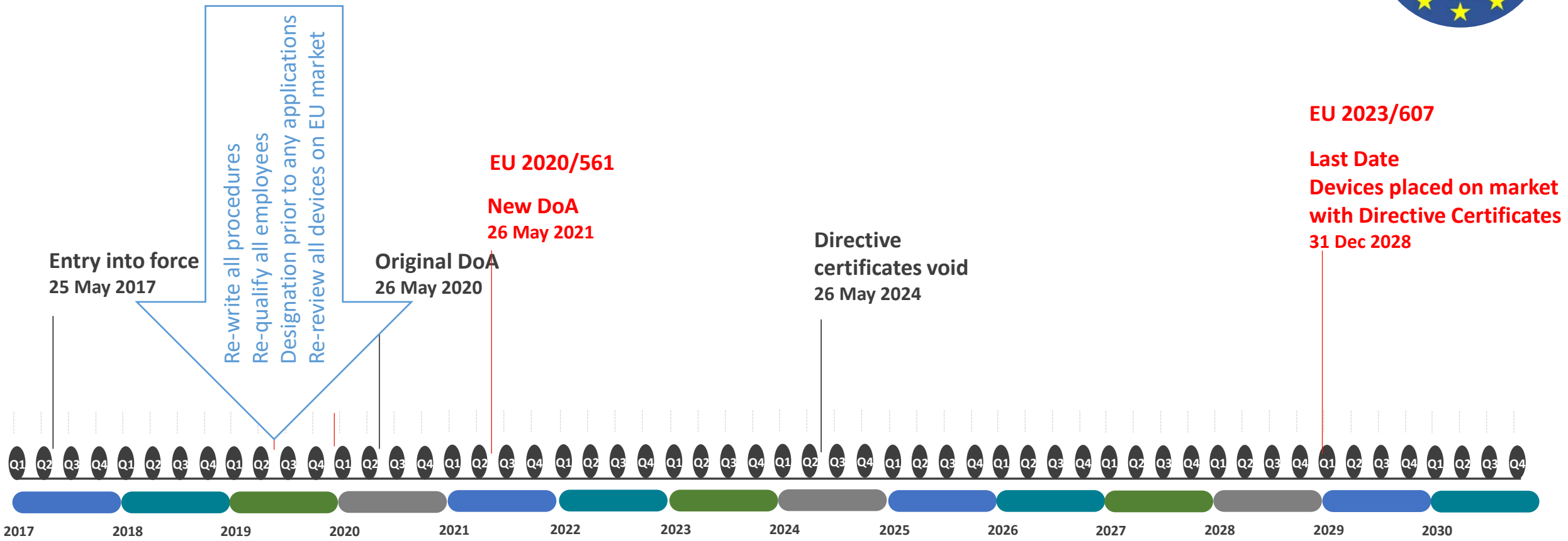
UDI

Implant Card

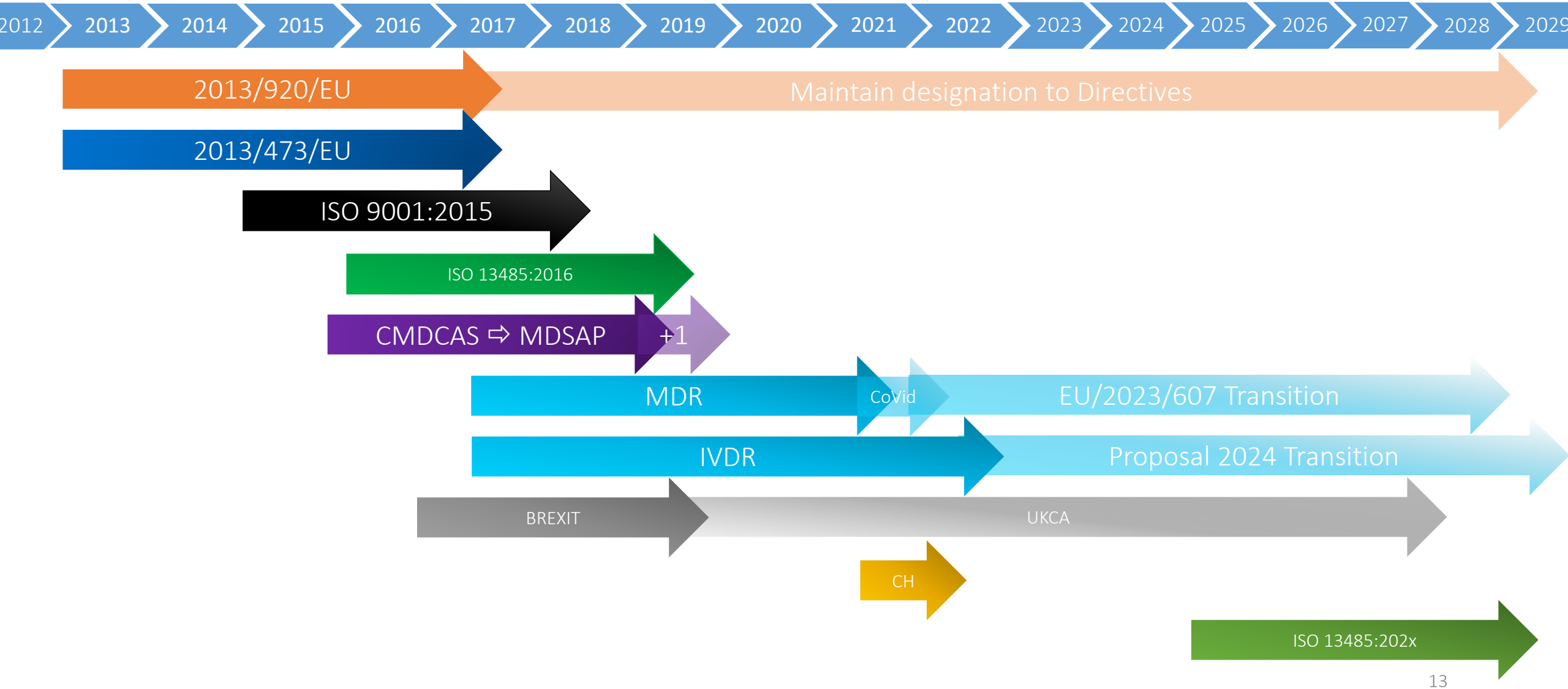
Incident reporting <15 days

PSUR / SSCP

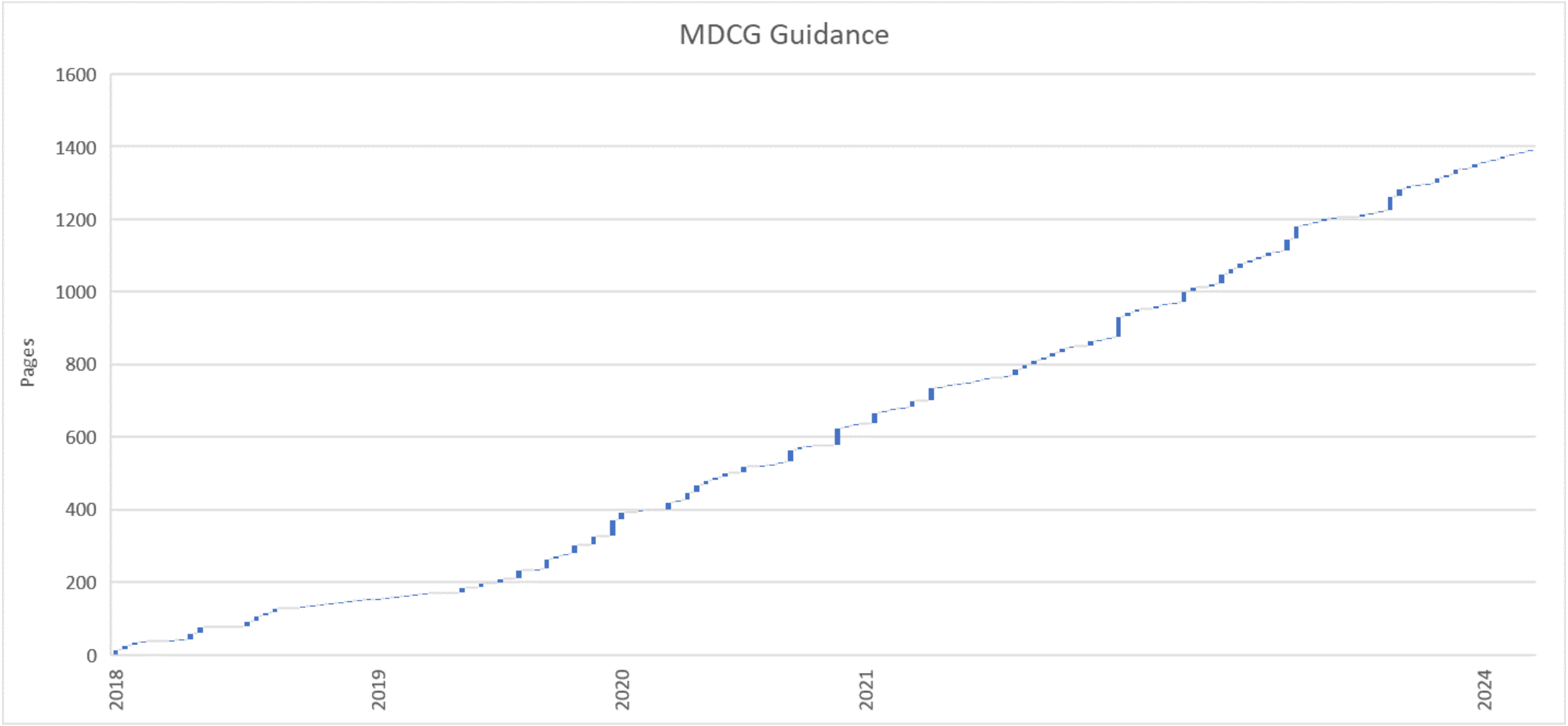
MDR Implementation



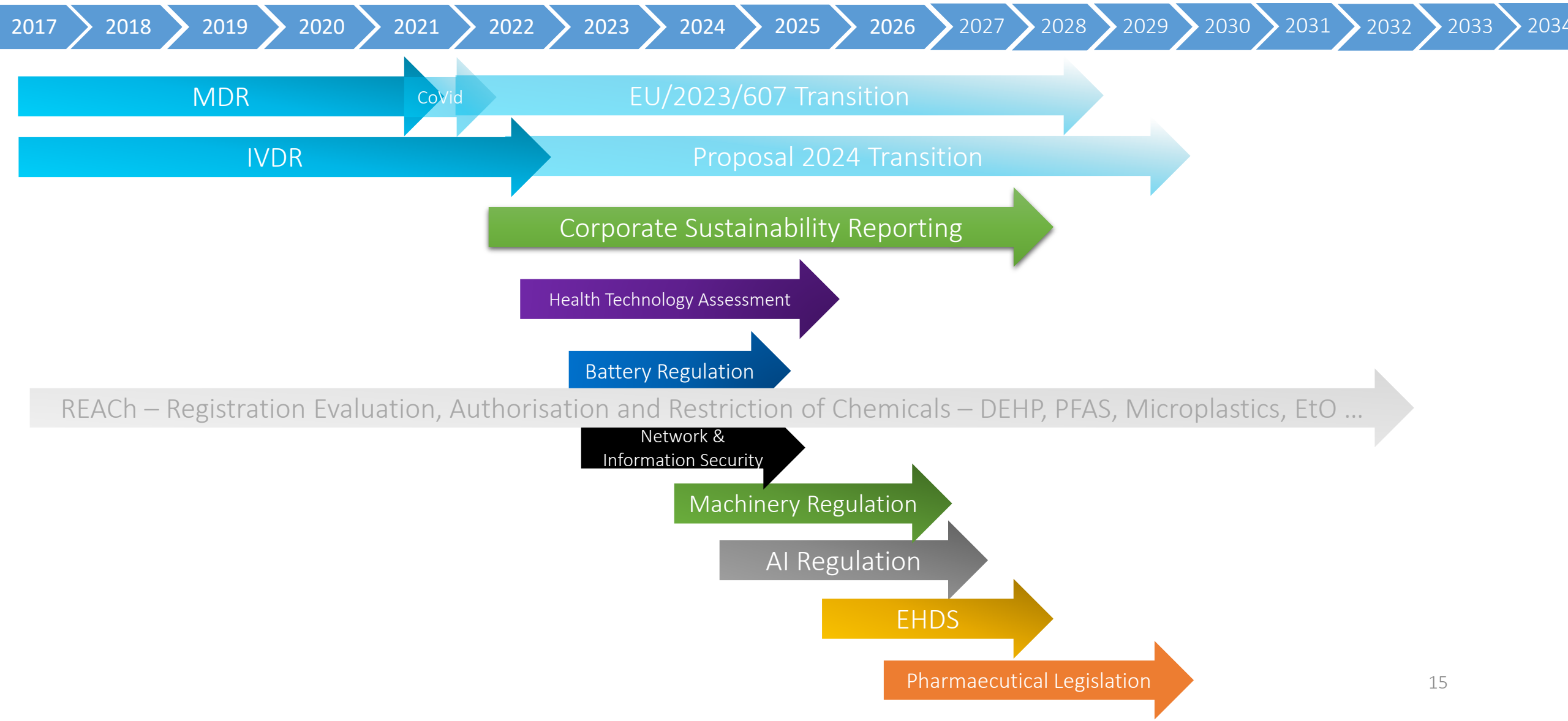
Medical Devices – Global Changes



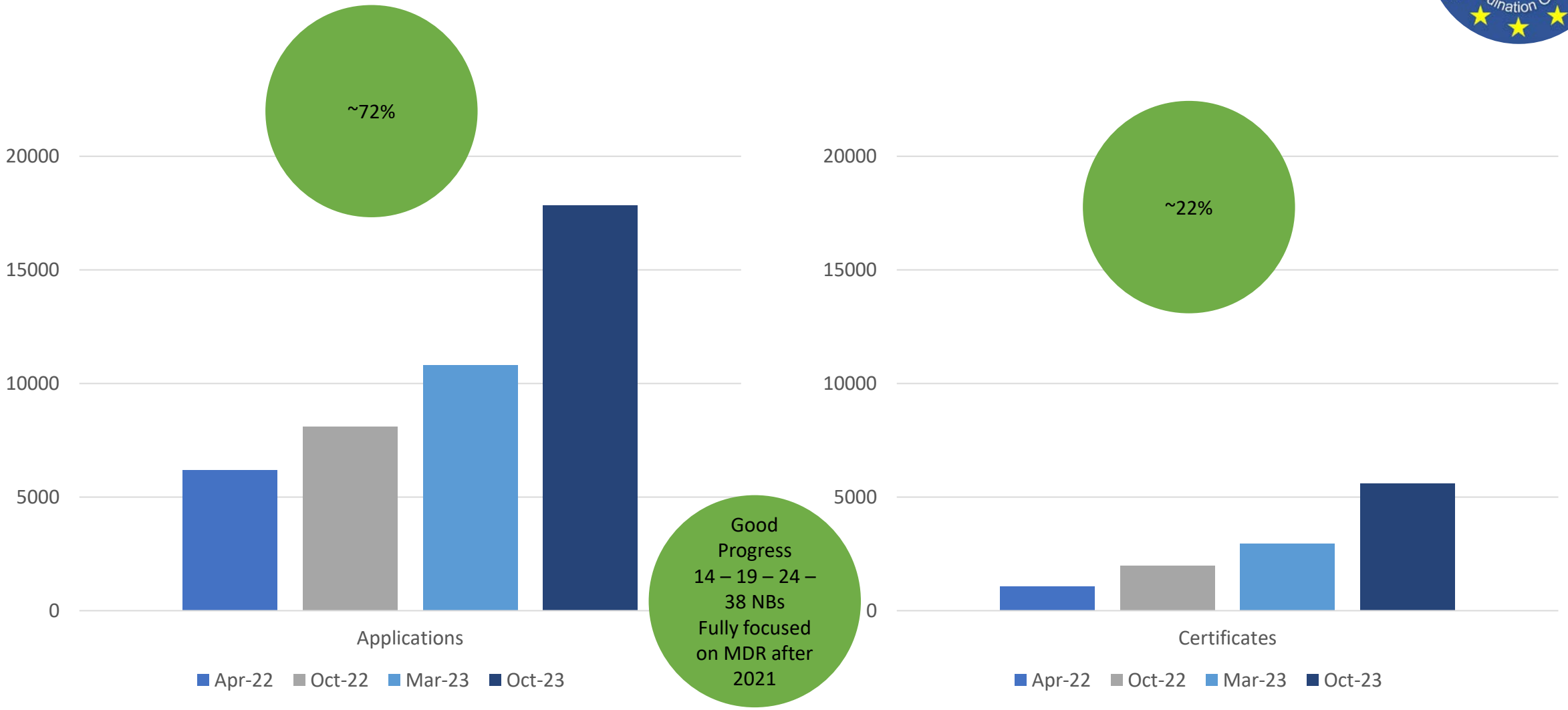
MDR Implementation



Medical Devices – EU Changes



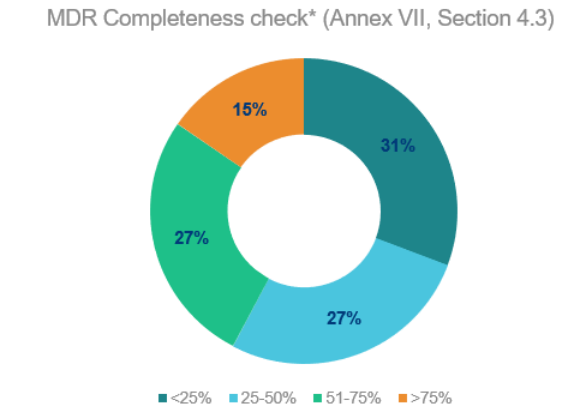
Transparency – Applications and Certificates



https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en

MDR – Completeness Check

Apr 2022

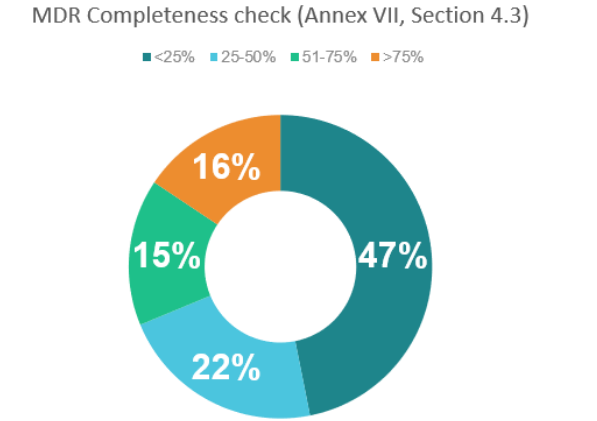


3/5 of NBs: less than 50% of submission are satisfactory in terms of documentation

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

58% of NBs said <50% of applications were complete

Oct 2022

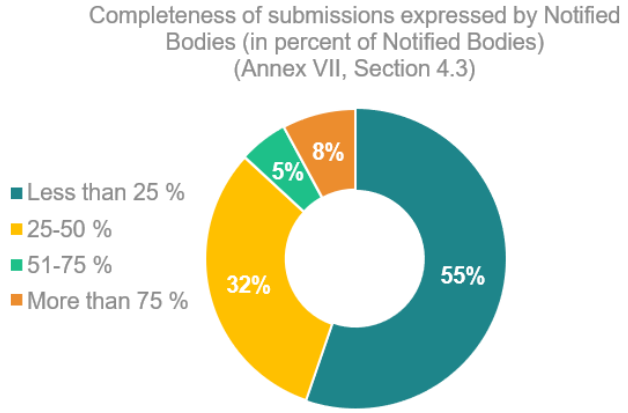


Several submissions deemed incomplete*

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

69% of NBs said <50% of applications were complete

Mar 2023



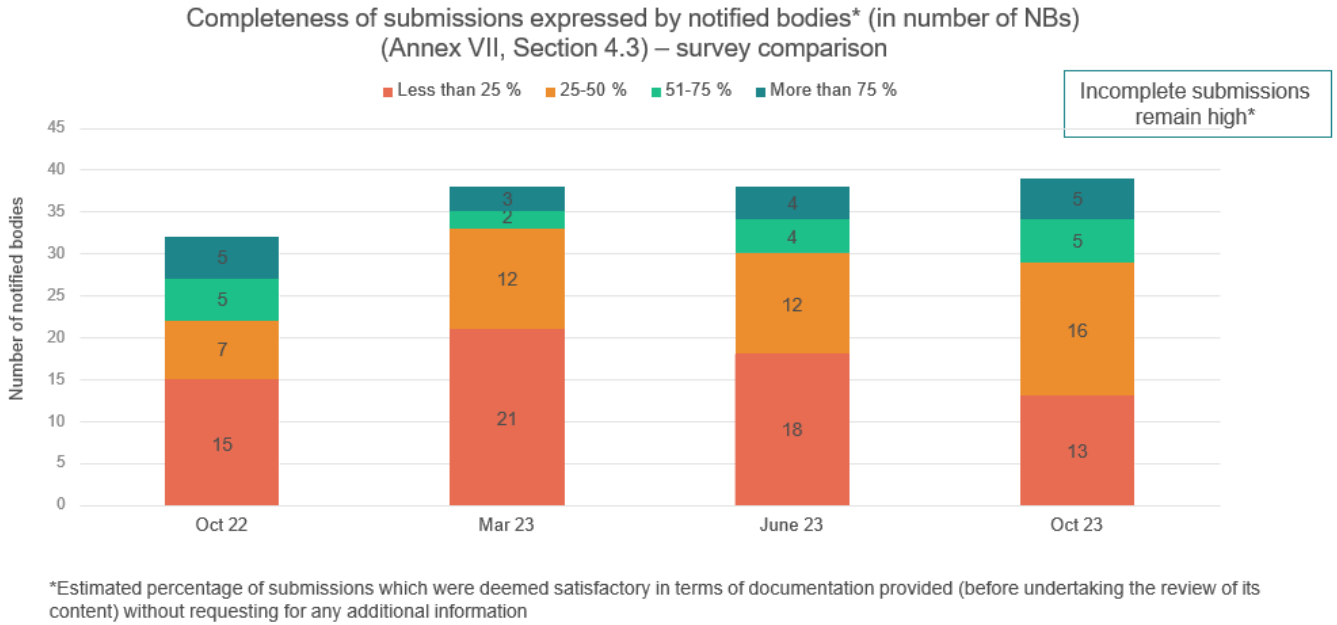
Several submissions deemed incomplete*

*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

87% of NBs said <50% of applications were complete

MDR – Completeness Check

Oct 2023



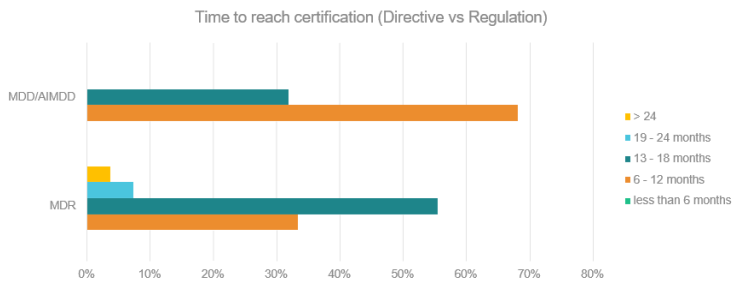
*Estimated percentage of submissions which were deemed satisfactory in terms of documentation provided (before undertaking the review of its content) without requesting for any additional information

74% of NBs said <50% of applications were complete

- In general we think these data show that manufacturers still need help
- Notified Bodies working on more consensus documents
- EU 2023/607 took considerable effort to 'appropriate surveillance of expired certificates' + some from other Notified Bodies + confirmation letters

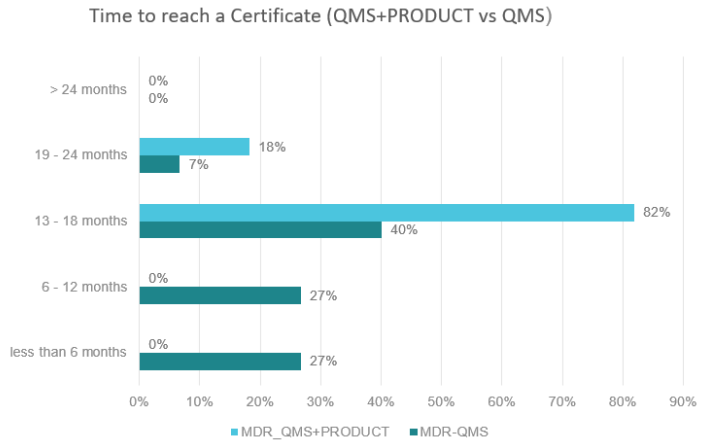
Predictability – Time to Certification

Apr 2022



33% of applications complete in 12 months

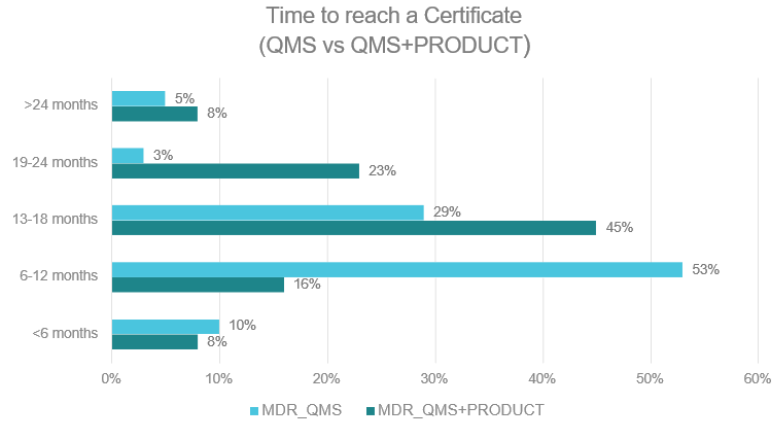
Oct 2022



54% of Class IIa & IIb applications complete in 12 months

0% of Class III and IIb implants (non-WET) applications complete in 12 months

Mar 2023

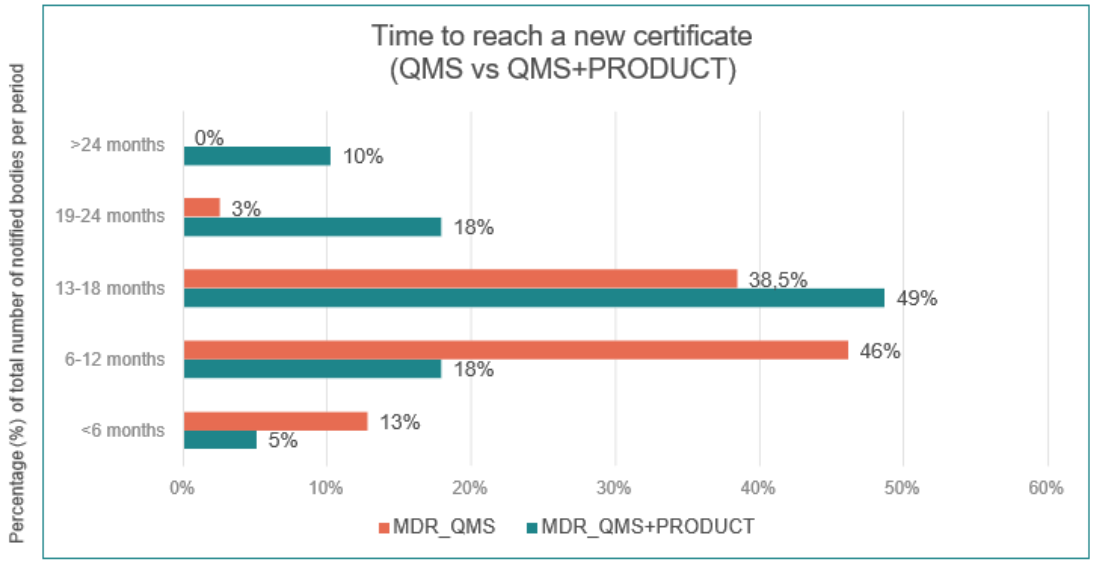


63% of Class IIa & IIb applications complete in 12 months

24% of Class III and IIb implants (non-WET) applications complete in 12 months

Predictability – Time to Certification

Oct 2023



Notes:

* The data shown comes from the medium data set – except for 2 NBs where the total number of applications filed was derived from the small data set Ⓢ since they could not provide the data per Annex.

- This indicator shows the time to reach issuance of a new EC certificate (from written agreement signed to issuance) under MDR.
- Some NBs have not issued a certificate yet, so the indicated time frame is an estimation.
- One NB stated that the proportion of complete documentation sets is slowly increasing.
- One NB stated to observe time periods to be increasing

59% of Class IIa & IIb applications complete in 12 months

23% of Class III and IIb implants (non-WET) applications complete in 12 months

- In general, we think these data show
  - NBs gaining experience in conducting conformity assessment
  - increase in confidence
- resulting in decreasing timelines

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Questions & Answers