

The New EU IVD Regulation & Brexit

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BIVDA

- 1** Some background: Directive vs Regulation
- 2** Purpose of IVDR
- 3** Regulatory Changes
- 4** Impact within the supply chain
- 5** Required Managerial Actions

Major Change of Regulatory Landscape EU

- The EU is undergoing a major change of Medical Device law moving from **Directives** to **Regulations** in **May 2017** There is a **transition period** (TP) for change implementation

EU Directives

Dedicated to single or all member states
Provisions have to be transposed into national law

In Vitro Diagnostics 98/79/EC

Medical Devices 93/42/EEC
AIMD 90/385/EEC

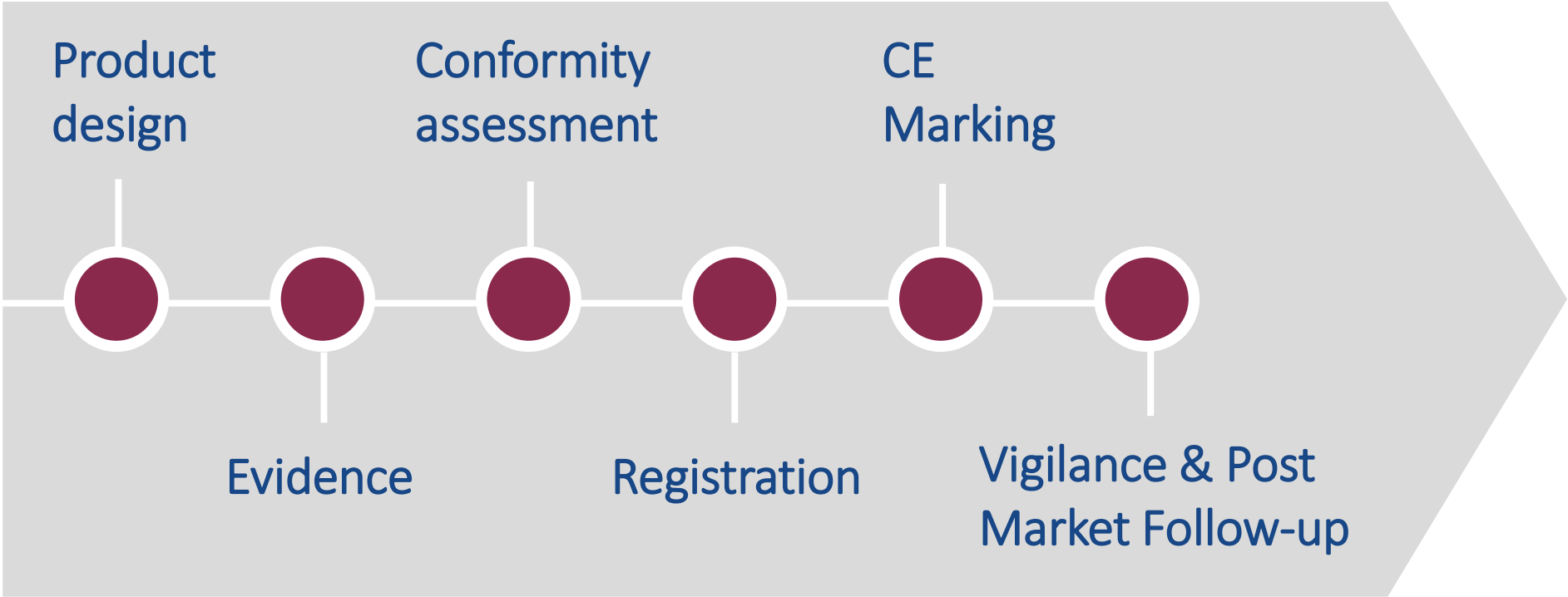
EU Regulation

EU legislation (no transposition into national law required)
National laws implementing Directives have to be repealed
Will come into force as indicated:

IVD Regulation (+5y TP – 2022)

MD Regulation (+3y TP - 2020)

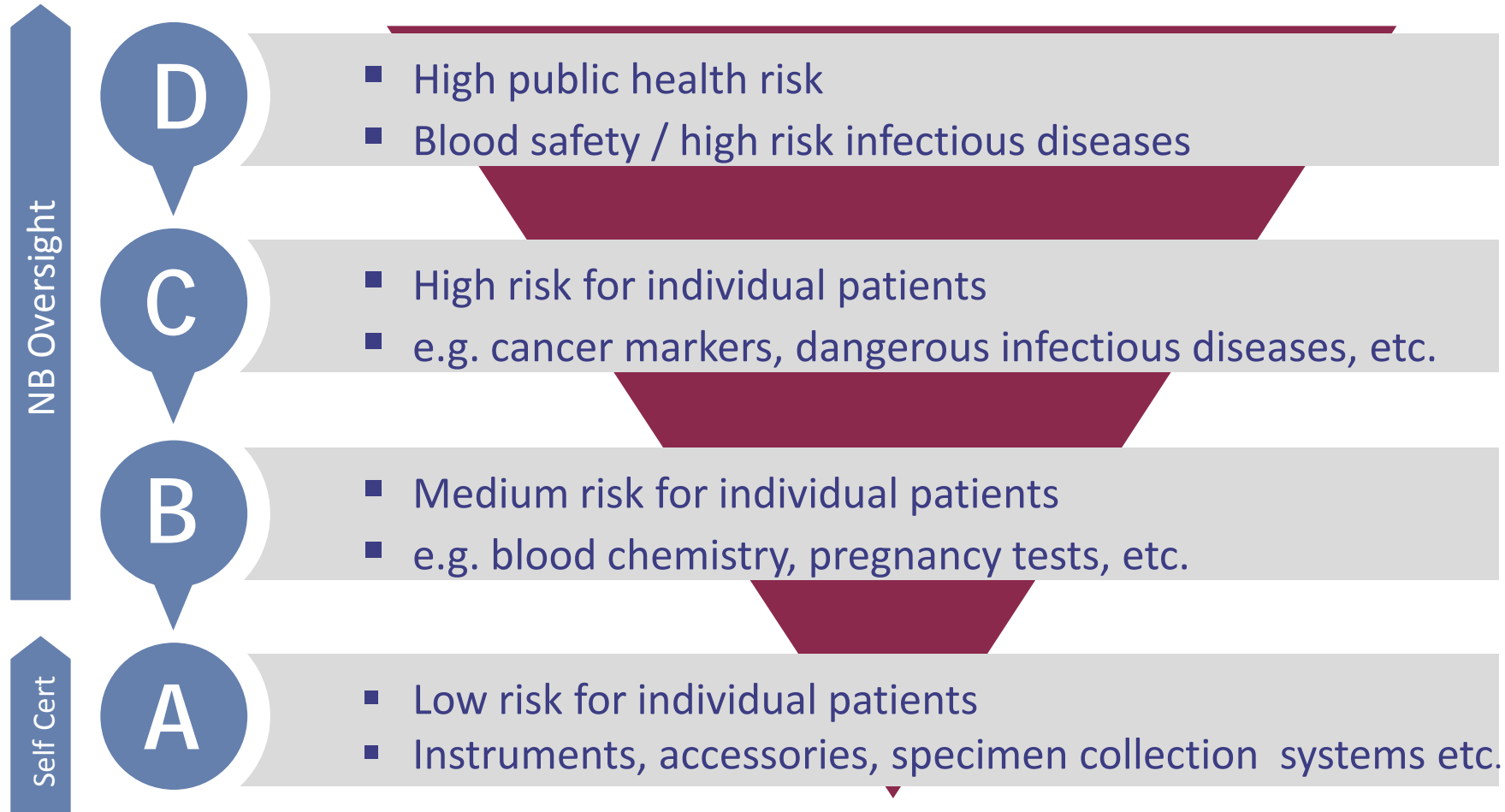
All Product Life Cycle Processes Are Affected



All IVDs same treatment

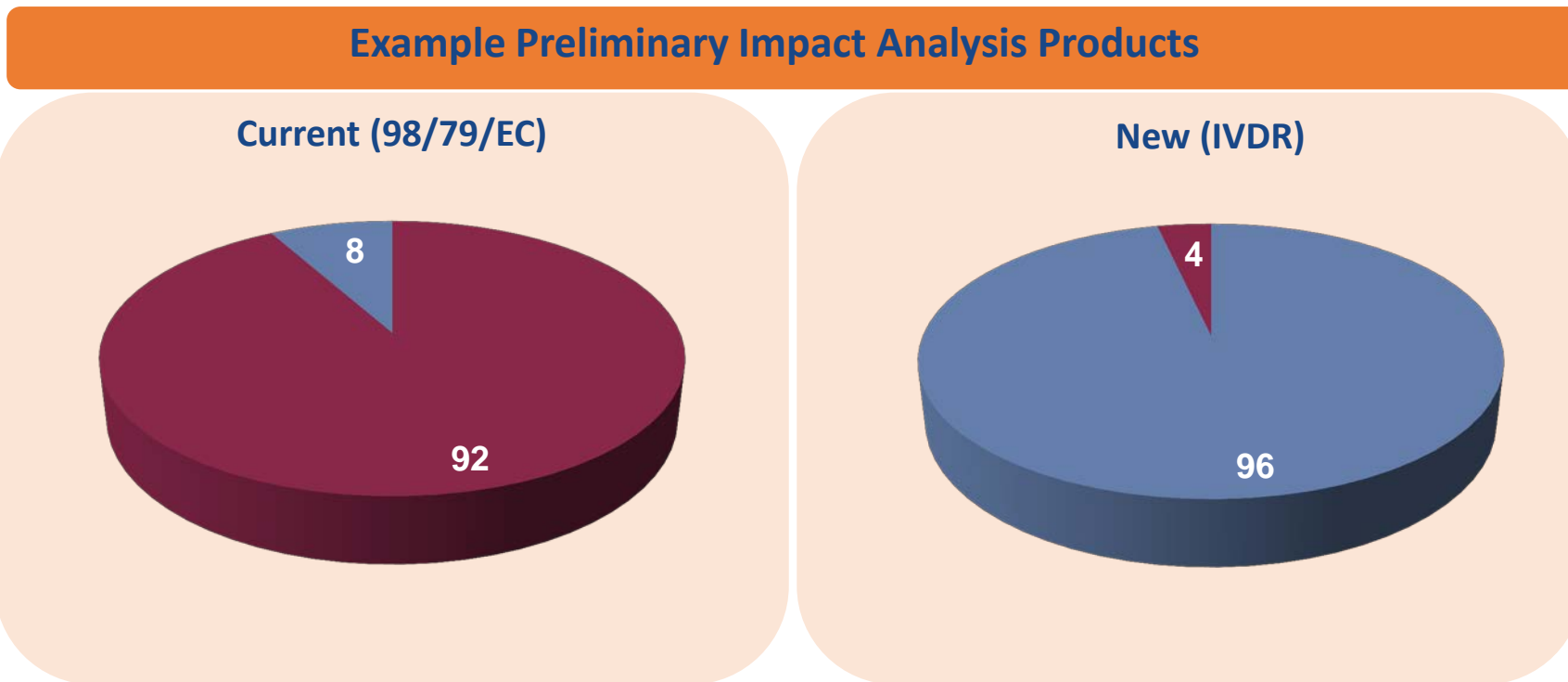
IVD Classification determines these steps

Key Change: New Classification System

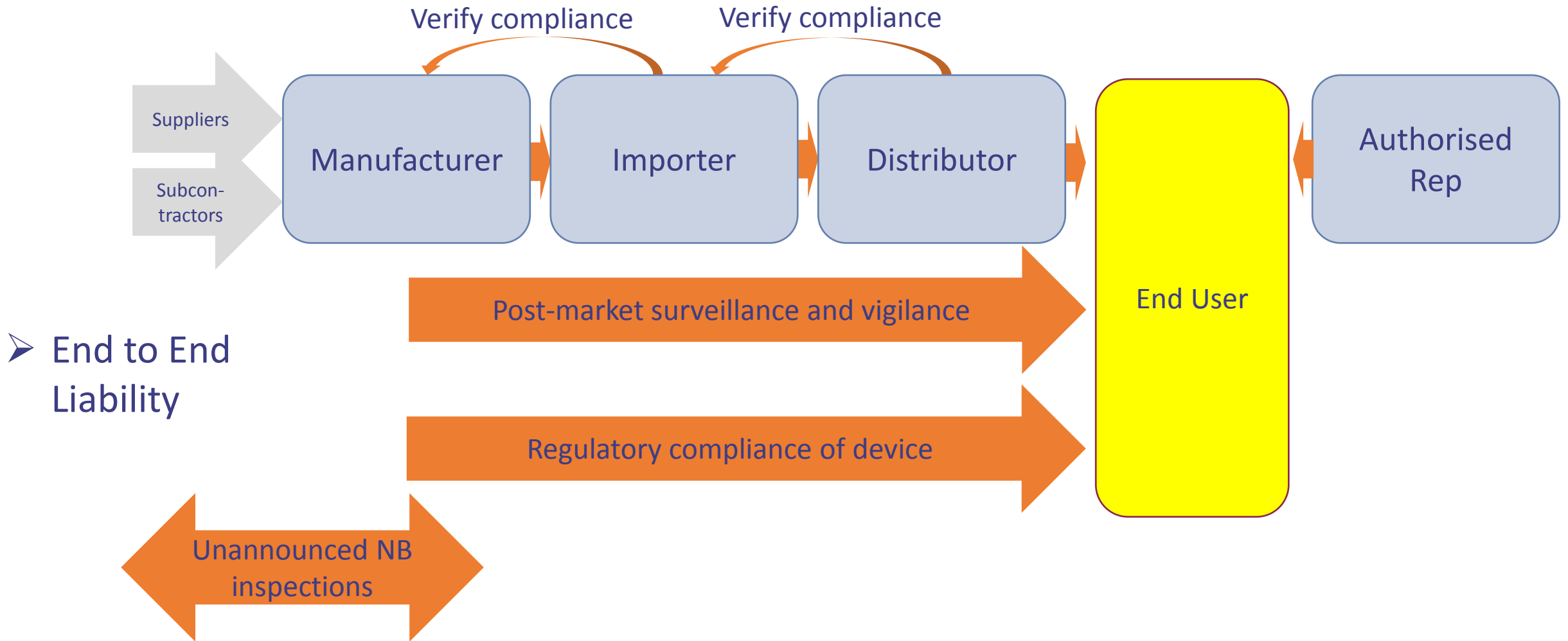


IVDR Reclassification Impact

- Leads to significant upclassification from manufacturer self-declared products to more stringently controlled risk classes requiring NB



Impact :MAID Economic Operators



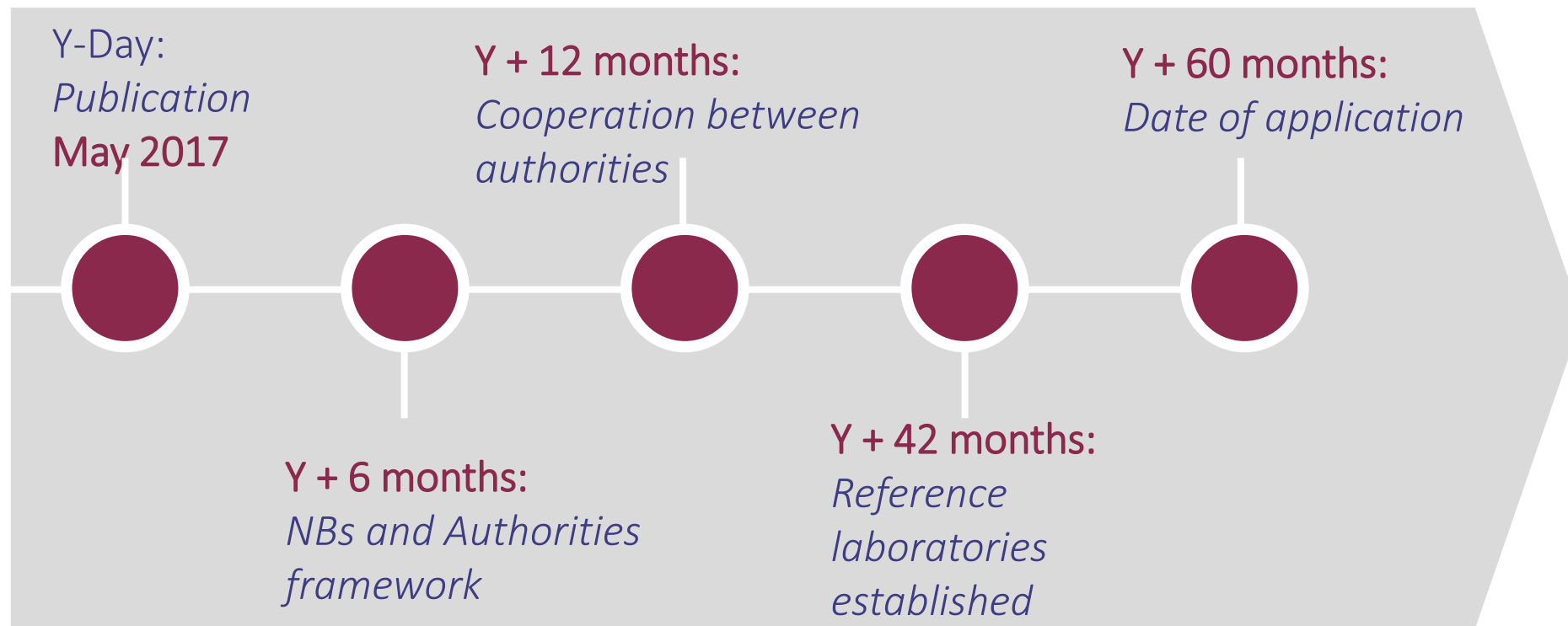
What is changing?

- No Grandfathering and product data, scientific validity of the test and particularly clinical data requirements are significantly increased.
- Many new requirements, e.g. Unique Device Identification, language requirements, (Technical) Documentation and labelling changes, transparency to the public, person responsible for regulatory compliance, registration and reporting in new EUDAMED database, training, testing at a distance, reference labs for product testing

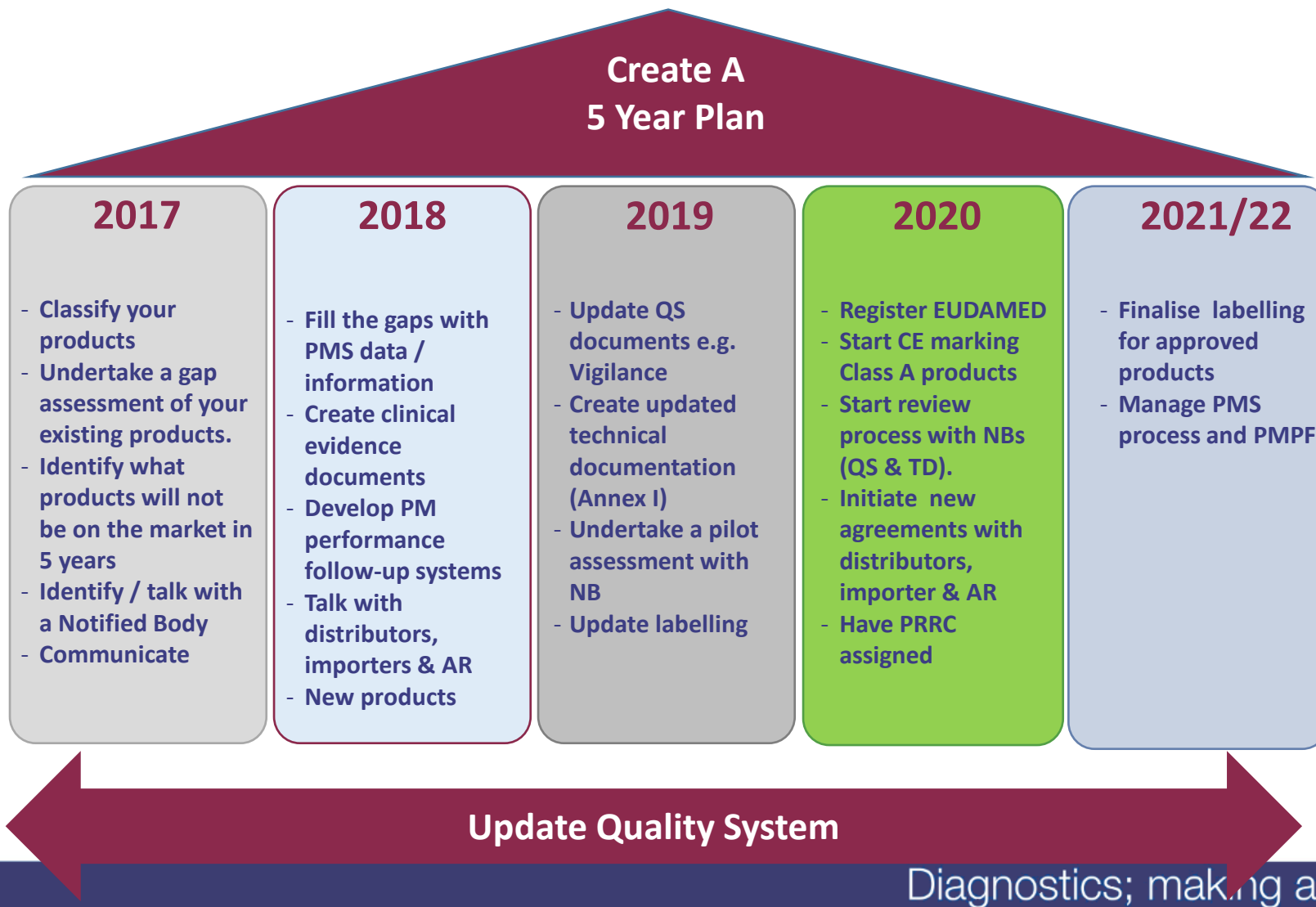
What is changing?

- Vigilance and Post Market Surveillance formalised and reporting increased and time is reduced.
- Liability requirements more defined across supply chain
- For high risk devices C+D manufacturers must summarise main safety and performance aspects of the devices together with performance evaluation and make this publicly available.
- Allows Country Authorities to levy fees

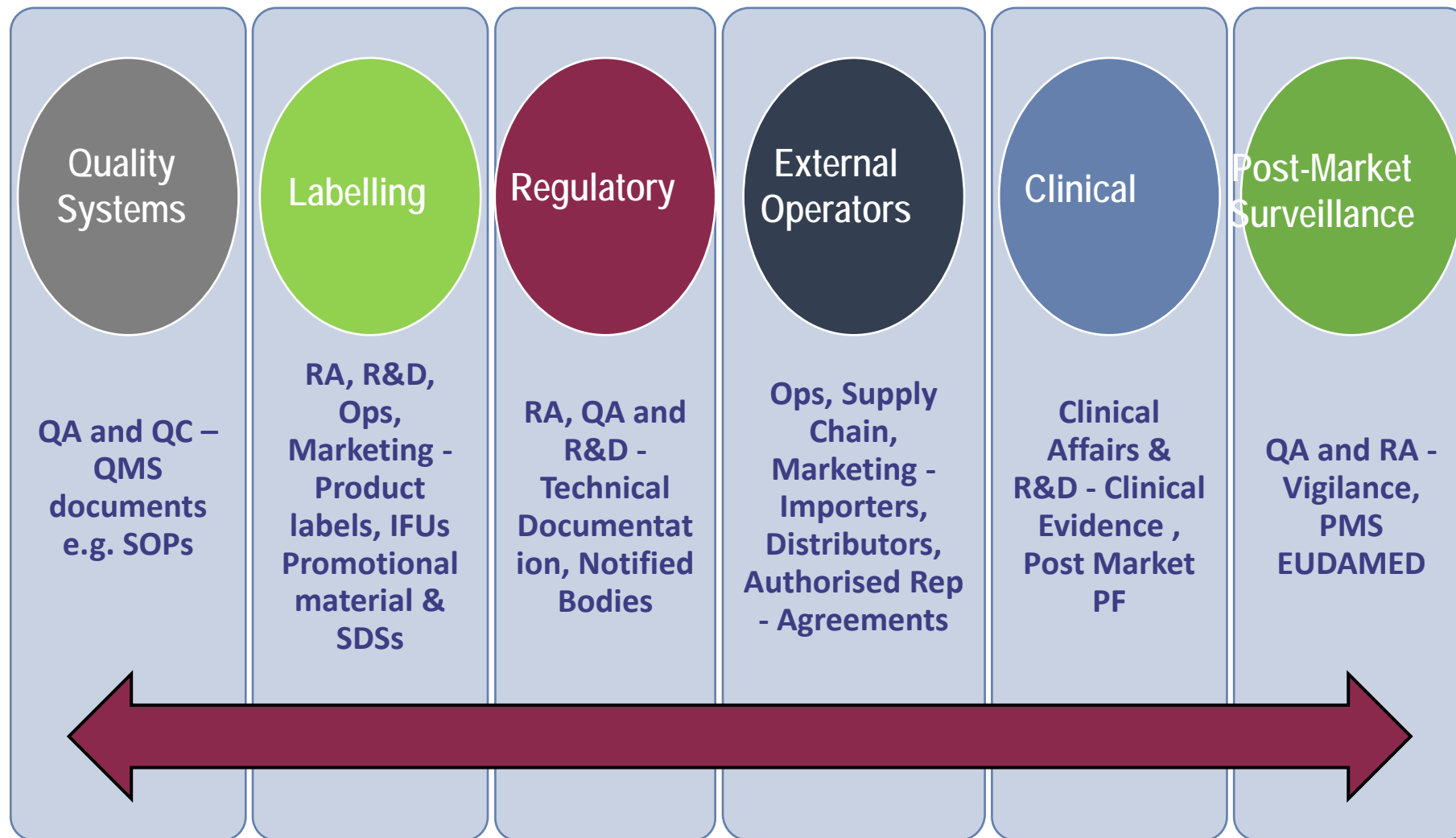
- There is a **5 year transition period** for implementation of IVDR requirements
- Certain prerequisites for IVDR will only become available during this period (e.g. NB accreditation, EUDAMED database, reference labs, info on fees)
- Some details of the legislation will be defined after adoption in further legal acts which will require continuation of advocacy



Action required?

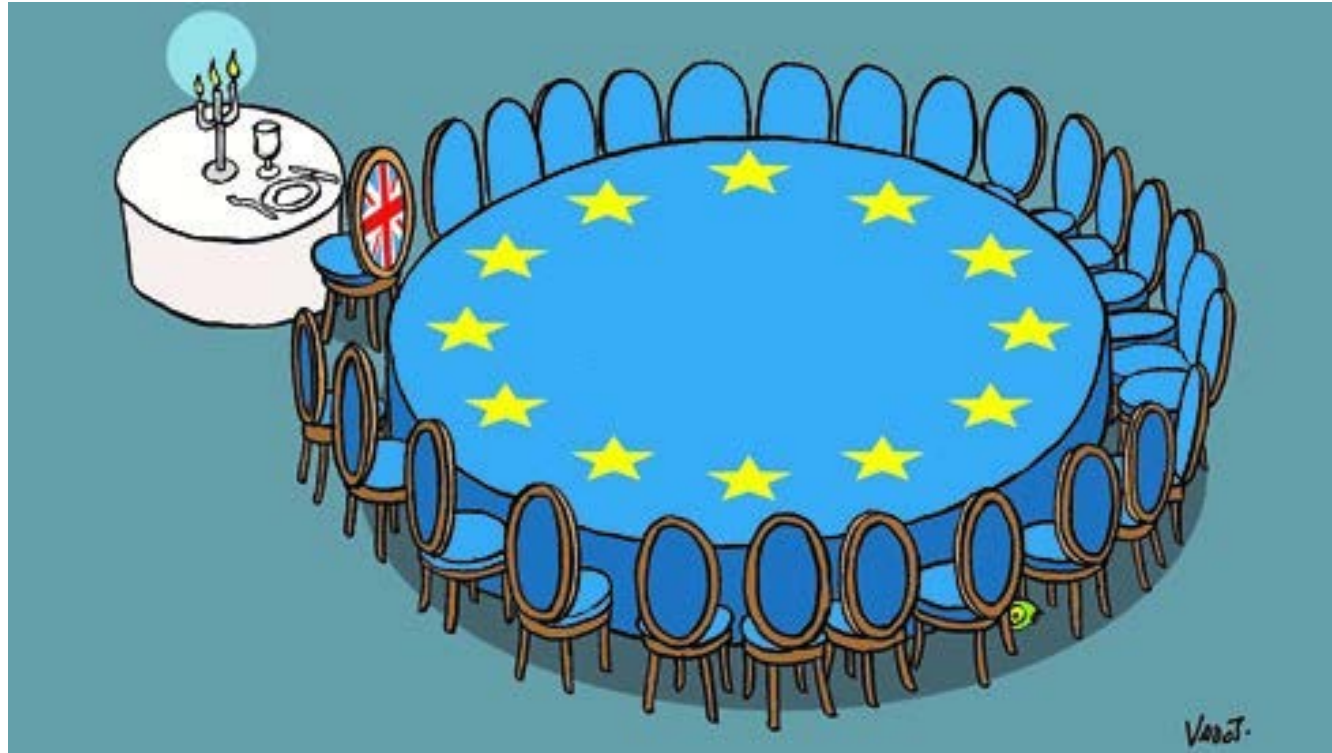


Involve everyone!



- Things will change as implementing acts, BREXIT, NB and other factors develop.
- BIVDA will continue to provide updates and oversight
- It's going to be “an interesting time”
- It's not going to be cheap ☹ Estimates £25-50K per product as one-off then ongoing NB fees, Vigilance levy etc
- PS – Don't forget other regulations such as the Biocidal Products Regulation (making it difficult to use chemicals such as Sodium Azide) and REACH (in 42 months from May 2017 use of Tritons will require authorisation)

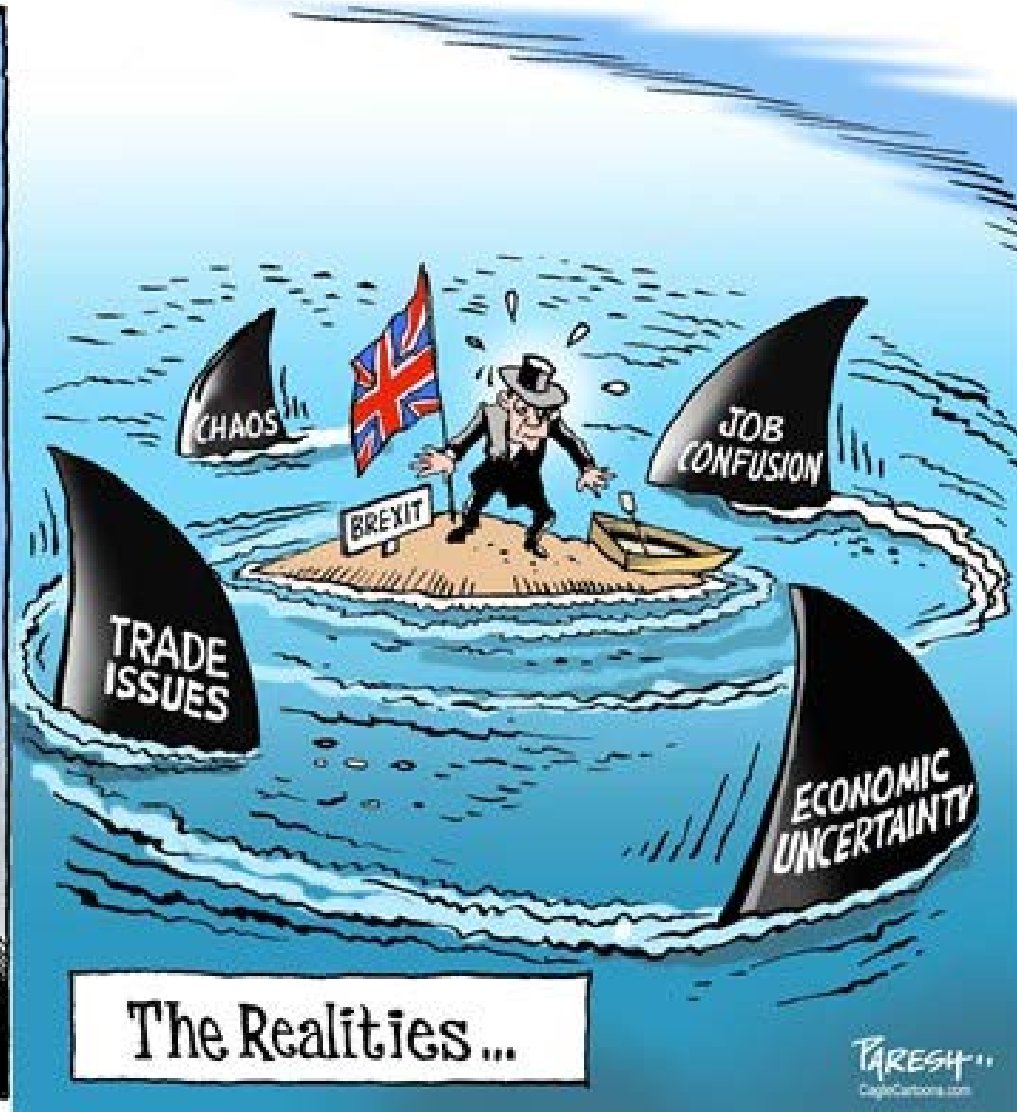
And now for Brexit...



**A forbidden term – We are Exiting the EU with
the assistance of Dept. for Exiting the Eu**

@DExEUgov

Temptation.....



What will Brexit mean?

- Frustratingly, nearly one year on from referendum we still don't really know
- IVD sector in common with other life science industry sectors (and healthcare and health research) are worried about the movement of people and access to skills
- Regulation is other main cause for concern

Effect on Regulation

- Worst case would be so-called 'hard Brexit' with no mutual recognition ie UK would have to implement it's own National laws to regulate IVDs
- To sell in the EU and access markets that recognise CE marking then UK manufacturers would need to employ an Authorised Representative who would need a QC/RA professional(s) to authorise batch release and oversee all compliance to regulation

8 IVD Sector 'Asks'

1. UK to set out long term R&D plans to ensure international collaboration in a positive environment
2. UK to harmonise regulations on collecting, use and/or sharing personal data with EU Data Protection Directive
3. UK to ensure IP policies consistent with EU – no extra burden for patent applications
4. UK to provide clarity for skilled workers in life sciences – no barriers to staying / entering

5. UK to align regulations with EU – prefer to use EU regulation if at all possible
6. UK to provide additional funding to support advances in the IVD sector so UK patients can benefit from clinical outcomes and cost savings
7. UK to ensure trade with EU continues and any volatility does not impact on NHS providing high quality services using IVDs
8. UK to ensure procurement regulations fit for purpose for NHS services and encourage innovation & adoption of new IVDs

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