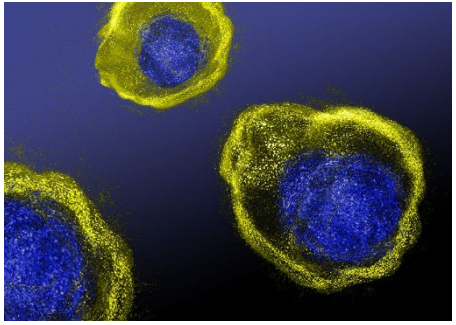
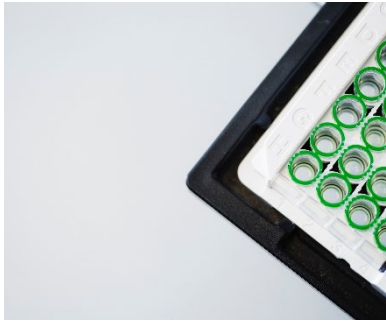


SVAR

Answers in Life Science



Answers in Life Science

IVDR

Status update on IVDR for Svar

Jesper Eriksson

Commercial Product Manager

Answers in Life Science

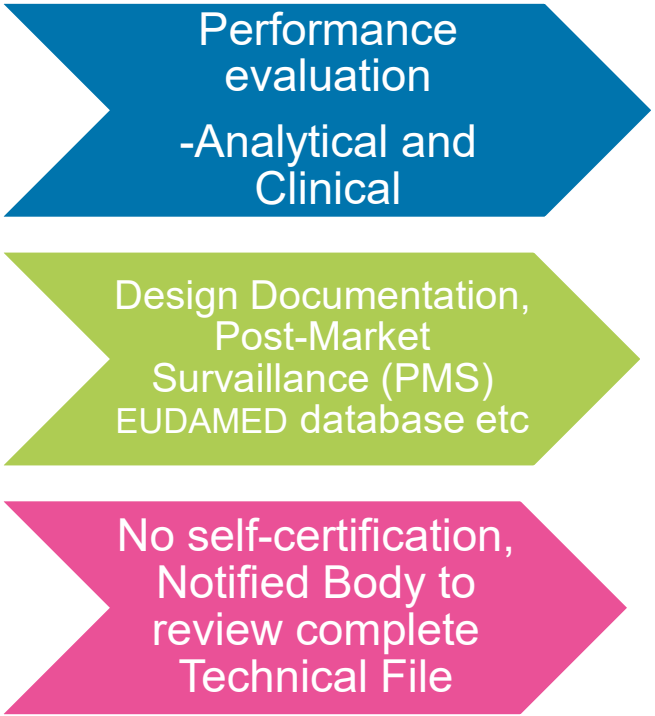
svarlifescience.com

Key objectives of IVDR

Enhanced Patient Safety - By requiring robust analytical and clinical evidence, the IVDR aims to ensure that IVDs deliver accurate and reliable results.

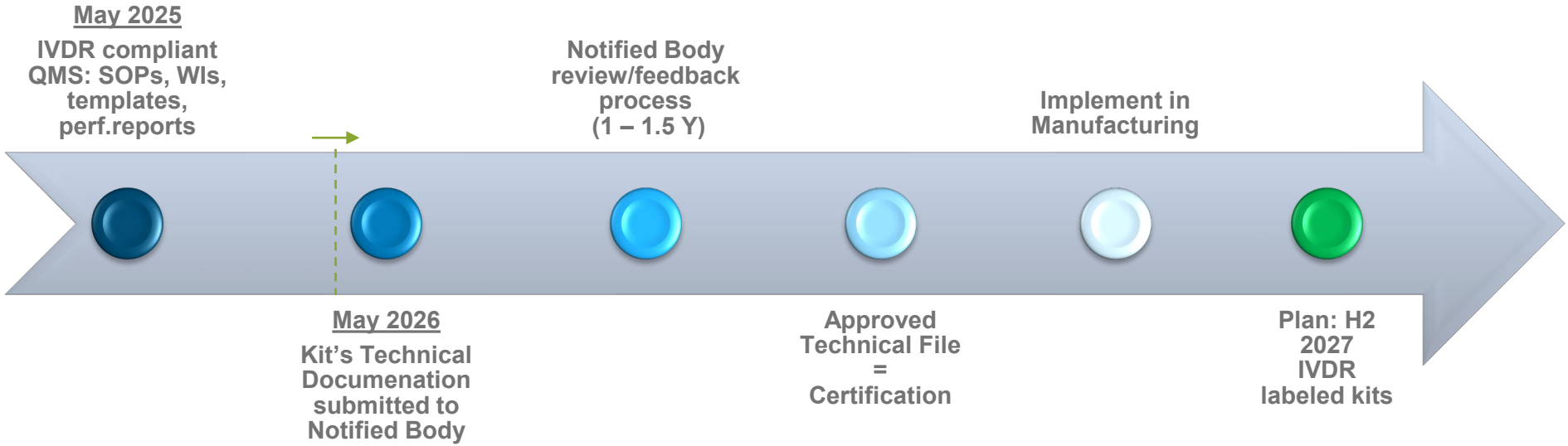
Improved transparency - Better reporting and documentation practices, ensuring that stakeholders are well-informed about IVD performance and safety.

Stricter Oversight - More rigorous oversight through detailed assessments by Notified Bodies, ensuring that IVDs meet the stringent criteria set out by the IVDR.



Timeline: IVDD towards IVDR

- **Before 2017: IVDD in force**
- **2017: Adoption of IVDR**
  EU adopted the IVDR to replace IVDD
- **2017 – 2022: Preparation and transition**
  The period between adoption and full application allowed industry and authorities to adapt
- **2022: IVDR becomes fully applicable**
  New IVDs placed on market (after May 2022) must be IVDR compliant
- **Post May 2022. Extended transition period until Dec 2029**
  EU allows IVDD compliant devices to remain on the market during transition window to avoid shortages
- **Dec 2029 – IVDR deadline for class B IVD devices**



Svar's five IVD kits for IVDR certification

Product name	Item code
IMMUNOSCAN CCPlus®	RA-96PLUS
WIESLAB® Complement system Classical pathway	COMPLCP310
WIESLAB® Complement system MBL pathway	COMPLMP320
WIESLAB® Complement system Alternative pathway	COMPLAP330
WIESLAB® Complement system Screen	COMPL300

Will be transferred from IVDD to IVDR

Will stay on the market under IVDD until IVDR approval

IVDR project – workload 2024 & 2025

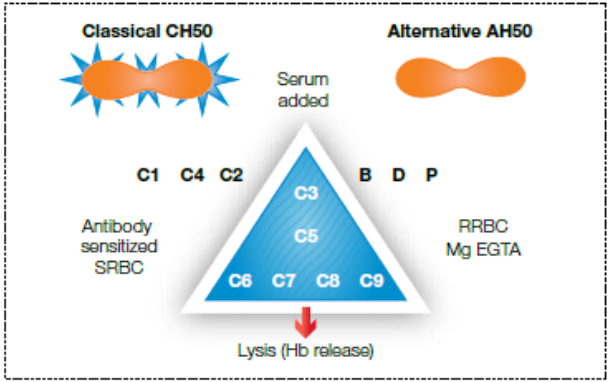
- **59 finalised reports**
- **More than 850 report pages**
- **200+ signatures**
- **7 full binders of lab-work and equipment documentation**
- **New performance evaluation data/reports for analytical and clinical performance indicators for the complement kits and CCPlus**

IVDR and distribution

- **The distribution contract we have today is already comprehensive**
- **Minor updates will be made regarding IVDR, we will come back to you**

Hemolytic lab developed tests and IVDR

- **Widespread method**
- **CH50: Classical pathway using antibody sensitized sheep RBC.**
- **AH50: Alternative pathway using rabbit RBC**
- **Many process steps – poor ease of use. Lot-to-lot calibration due to animal RBC.**
- **Unlikely to be certified under IVDR**



SE case: 40 hemolytic tests per week. Approx. 750K people uptake area. Translates to 70 kit/million rate per year.

Thank you