**Introduction**

- In Vitro Diagnostic Device Regulation (IVDR) is new European regulation for placing in vitro diagnostic medical devices (IVDMD) on the European market.
- Revision of the current Directive 98/79/EC was done to establish a robust, transparent, predictable and sustainable regulatory framework for IVDMD which ensures high level of safety and health whilst supporting innovation. This regulation sets high standards of quality and safety for IVDMD by ensuring, among other things, that data generated in performance studies is reliable and robust.
- Here we show a robust project plan to fulfill IVDR requirements of more than 230 IVD CE marked products for May 2022.

**Aim**

- Beckman Coulter (BEC) has put in place an intensive worldwide program across all Business Units (BU) in order to meet the quality and safety standards requirements in a timely manner. This Global IVDR program aims to identify and remediate impacts for all current BEC IVD products to comply with In Vitro Diagnostic Device Regulation.

**Strategy**

1. Identification of a need for clinical evidence
2. Analytical performance
3. Scientific validity
4. Clinical performance
5. Intended use
6. Intended purpose
7. Post Market Surveillance
8. Classification & Conformance roadmap
9. Technical file structure according to (EU) 2017/746 regulation

**Conclusion**

New IVDMD classification demands demonstration of strong clinical evidence, which resides in Analytical Performance, Scientific Validity and Clinical Performance. BEC Marseille IVDR team, in the framework of the IVDR Global program, has established and deployed a robust project plan to fulfill IVDR requirements of more than 230 IVD CE marked products for May 2022. One key of success is strong and open relationship between different stakeholders such as Quality/Regulatory Affairs, R&D, Manufacturing, Engineering and Marketing.