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IVDR The Executive Summary

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Your MedTech Partner for **Regulatory, Quality, and Clinical Trials**
Europe - The Netherlands - Germany - United Kingkom | USA - Massachusetts - California | China - Nanjing

3 Key things you need to know about the IVDR

TIPS OF THE DAY

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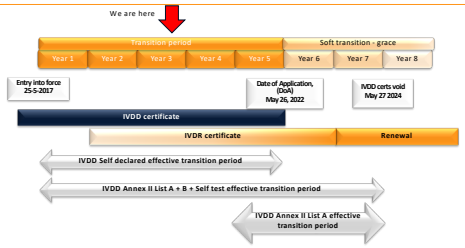
Transitioning details – IVDR



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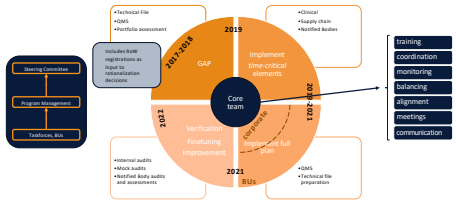
Implementation Status

15%	• Not started
75%	• Creating gap analysis and reviewing product portfolio
10%	• Prepared initial pilot TFs + implementing new procedures for the QMS

IVDR implementation activities

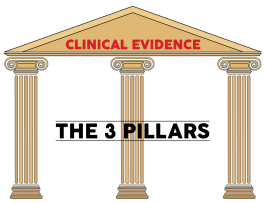


Feedback from the field

Feedback from those who have done a gap analysis revealed some common gaps

- **Stability**
  - Review of stability data often finds missing time points to support current expiry dates
  - It will take time to create fresh data
- **Clinical evidence**
  - New reports required
  - Often analytical but insufficient clinical performance data

Clinical Evidence



'clinical evidence' means the clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer

Documented in a Performance Evaluation Report

Clinical Evidence

- Scientific validity of an analyte means the association of an analyte to a clinical condition or a physiological state;
- Analytical performance means the ability of a device to correctly detect or measure a particular analyte
- Clinical performance means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user

Clinical utility not required

NO
Grandfathering

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TIME Is

RUNNING OUT

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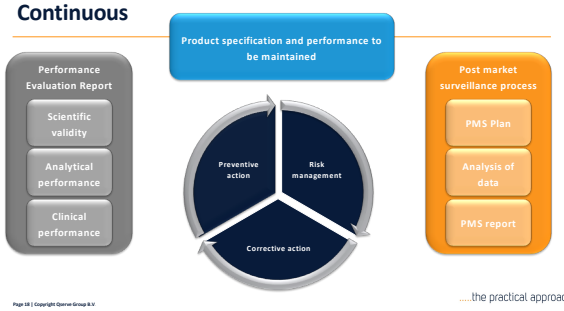
The devil is in the detail

Prescriptive detail

- Performance evaluation plan,
- Performance study plan
- Clinical performance study plan
- Post-market surveillance plan
- Post Market performance follow-up Plan
- Risk management Plan
- Corrective and preventive action plan
- Performance evaluation report
- Performance study report
- Post-market surveillance report
- Scientific validity report
- Analytical performance report
- Clinical performance report
- Complaint report
- Vigilance report
- Trend report
- Periodic safety update report

Continuous



Resource

- Extra work to create and maintain new IVDR Plans and reports
- Not all the extra resource required will come from Regulatory and Quality

Finally.....

- IVDR will be subject to revision through implementing acts
- Expectations are likely to increase with experience
- Approval times will increase and will need to be factored into design programs
- Whilst there will be a bolus of activity to achieve compliance to the IVDR significant effort will be required to continue to meet the requirements and maintain the system
- Planning ahead and keeping on top of forthcoming changes will be essential to staying ahead in the future