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## Safety and performance of high-risk medical devices: the role of real-world data

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## **Safety and performance of high-risk medical devices: the role of real-world data**

1. The large heterogeneity in data reported and methodological characteristics of arthroplasty and cardiovascular registries determine the quality and utility of registry data for postmarketing surveillance. *This thesis.*
2. To improve the detection of safety signals for medical devices, a multifaceted approach is needed that integrates various real-world data sources and analytical methods. *This thesis.*
3. Although intended to improve patient safety, the European Medical Device Regulation creates challenges before safe and scientifically proven medical devices can be used in clinical practice. *This thesis.*
4. The outcome of total knee implant performance across registries should be taken with caution since patient characteristics show large variety. *This thesis.*
5. The clinical evidence of safety and efficacy for many high-risk medical devices needs to be strengthened. *Adapted from Fraser, et al. Recommended methodologies for clinical investigations of high-risk medical devices – Conclusions from the European Union CORE–MD Project.*
6. Real-world data (RWD) play an increasingly important role in orthopaedics as demonstrated by the rapidly growing number of publications using registry, administrative, and other databases. Each type of RWD source has its strengths and weaknesses, as does each specific database. *Adapted from Hak, et al. Real-World Evidence: A Review of Real-World Data Sources Used in Orthopaedic Research.*
7. Ensuring the safety and reliability of medical devices requires a delicate balance between innovation and rigorous oversight, managed through the collaborative efforts of standards development organizations, standards accrediting organizations, and regulatory agencies such as the U.S. Food and Drug Administration and the European Medicines Agency. *Adapted from Daryanani et al. Ensuring Medical Device Safety: The Role of Standards Organizations and Regulatory Bodies.*
8. Without data, you're just another person with an opinion. *William Edwards Deming – een promotietraject is een voortschrijdend inzicht proces, waar meningen veranderen door data te interpreteren.*
9. Je gaat het pas zien als je het doorhebt. *Johan Cruijff - Je gaat het pas zien als je het doorhebt. Pieter Winsemius (27 January 2017). Over data analyseren en interpreteren.*
10. We're all part of the masterplan. *Oasis – the Masterplan (2 November 1998). Een promotietraject is het resultaat van samenwerking.*