



Universiteit  
Leiden  
The Netherlands

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

Hoogervorst, L.A.

### Citation

Hoogervorst, L. A. (2025, November 18). *Safety and performance of high-risk medical devices: the role of real-world data*. Retrieved from <https://hdl.handle.net/1887/4283146>

Version: Publisher's Version

License: [Licence agreement concerning inclusion of doctoral thesis in the Institutional Repository of the University of Leiden](#)

Downloaded from: <https://hdl.handle.net/1887/4283146>

**Note:** To cite this publication please use the final published version (if applicable).

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

*Lotje Anna Hoogervorst*

**Cover design and layout:** Lotje Hoogervorst, Meike Hoogervorst,  
Bente Hoogervorst, and Dick Hoogervorst

**Printing:** FritsPrint, Hoorn

**Copyright© 2022 by Lotje A. Hoogervorst**

All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means without permission in writing from the author. The copyright of the articles has been transferred to the respective journals.

The conduction of the research included in this thesis was carried out at the Departments of Orthopaedics & Biomedical Data Sciences, Medical Decision Making of the Leiden University Medical Center, Leiden, the Netherlands.

The studies conducted in Chapters 2 to 7 were financed by a grant from the European Union's Horizon (grant agreement: 965246) and were part of the Coordinating Research and Evidence for Medical Devices (CORE-MD) project.

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

Proefschrift

ter verkrijging van

de graad van doctor aan de Universiteit Leiden,

op gezag van rector magnificus prof.dr.ir. H. Bijl,

volgens besluit van het college voor promoties

te verdedigen op dinsdag 18 november 2025

klokke 16:00 uur

door

**Lotje Anna Hoogervorst**

geboren te Hoorn

in 1995

**Promotor(es)**

Prof.dr. R.G.H.H. Nelissen

Dr. P.J. Marang-van de Mheen

Delft University of Technology, Netherlands

**Leden promotiecommissie**

Prof.dr. S. Cannegieter

Prof.dr. M. Schali

Prof.dr. A. Pedersen

Dr. T. Melvin

Aarhus University, Denmark

University of Galway, Ireland

*Hello*  
*I've waited here for you*  
*Everlong*  
- Foo Fighters

## Table of contents

|                                 |                                                                                                                                                                                                                                                                      |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Chapter 1</b> (page 8-23)    | <b>General introduction and outline of the thesis</b>                                                                                                                                                                                                                |
| <b>Chapter 2</b> (page 24-48)   | <b>Quality and utility of European cardiovascular and orthopaedic registries for the regulatory evaluation of medical device safety and performance across the Implant lifecycle: a systematic review</b><br><i>Int J Health Policy Manag. 2023;12:7648</i>          |
| <b>Chapter 3</b> (page 49-75)   | <b>Development of a minimum checklist to assess the quality of evidence produced using registry data for the evaluation of medical device safety and performance</b><br><i>Submitted to BMJ Surgery</i>                                                              |
| <b>Chapter 4</b> (page 76-107)  | <b>Safety notices and registry outlier data measure different aspects of safety and performance of total knee implants</b><br><i>Acta Orthop. 2024 Nov 25;95:667-676</i>                                                                                             |
| <b>Chapter 5</b> (page 108-129) | <b>Frequency of safety signals from scientific reports, manufactures, registers, and other sources for a random selection of hip and knee prostheses</b><br><i>Acta Orthop. 2025 Jun 25;96:460-466</i>                                                               |
| <b>Chapter 6</b> (page 130-157) | <b>Validating Orthopaedic Data Evaluation Panel (ODEP) ratings across 9 orthopaedic registries: total hip implants with an ODEP rating perform better than those without an ODEP rating</b><br><i>J Bone Joint Surg Am. 2024 Sep 4;106(17):1583-1593</i>             |
| <b>Chapter 7</b> (page 158-180) | <b>Pooling data for primary total knee implants across registries: is the same implant used in multiple registries and for the same patient group?</b><br><i>Acta Orthop. 2025 Apr 17;96:339-347</i>                                                                 |
| <b>Chapter 8</b> (page 181-203) | <b>The reliability of revision rates following primary shoulder arthroplasty as a quality indicator to rank hospital performance: a national registry analysis including 13,104 shoulders and 87 hospitals</b><br><i>J Shoulder Elbow Surg. 2023 Jan;32(1):59-67</i> |

**Chapter 9** (page 204-224) **Summary, implications for clinical and regulatory practice, and future perspectives**

**Chapter 10** (page 225-241) **Summary in Dutch, bibliography, Curriculum Vitae, and acknowledgements**