

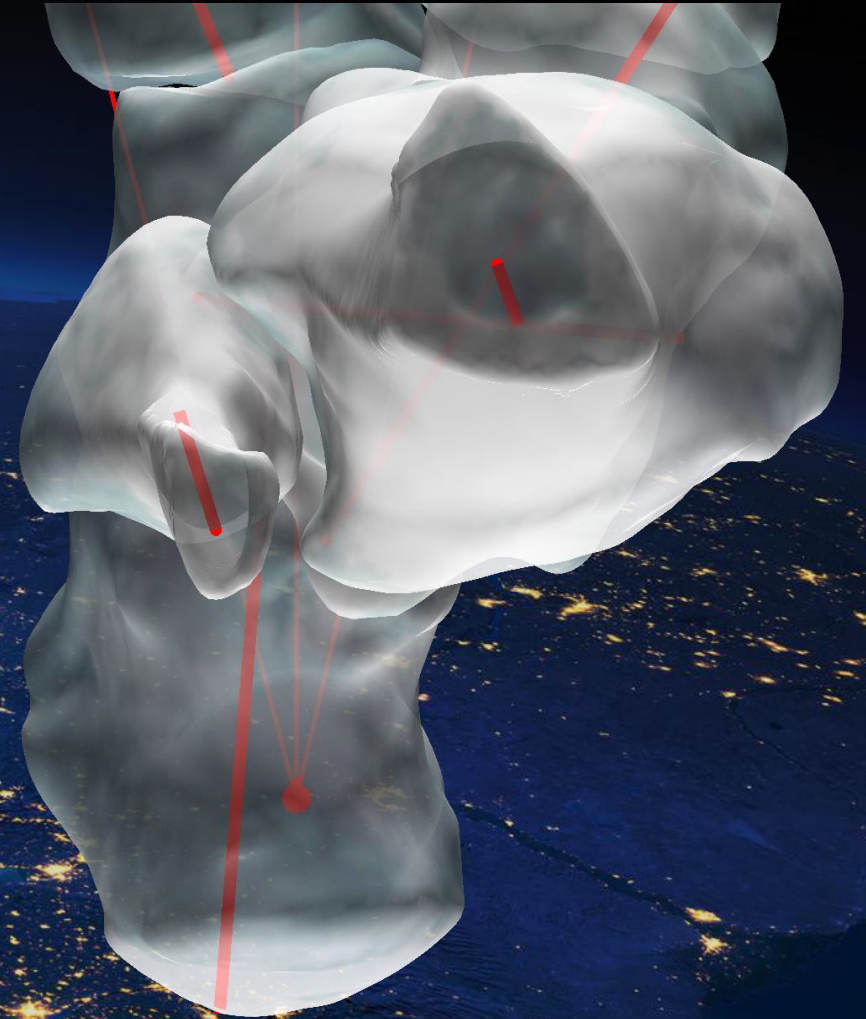


Making Medical Imaging Intelligent

HEALTH TUESDAY 05.05.2020

*Medical Device Regulations;
Startup Perspective*

Sakari Soini
Co-Founder & CTO @Disior

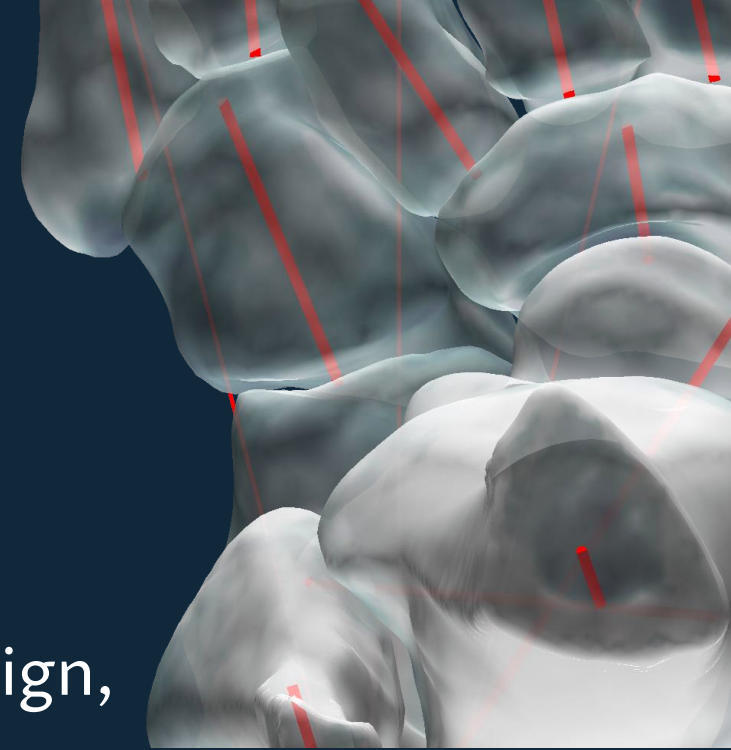


Disior in Brief

Finnish MedTech start-up, founded 2016

Develops Medical Image Analysis software

- Consistent, fast and accurate analysis
- Objective data for diagnosis and treatment planning
- Mathematical models for 3D printing and implant design, treatment analysis



Fracture line detection
and ossification follow up

User defined PSI for
reconstruction

Joint space /
cartilage analysis

Former Nokia leaders with a balanced team of technology and medical experts



Anna-Maria Henell
Co-Founder & CEO

Previously at Nokia

–
New technology
introduction lead



Sakari Soini
Co-Founder & CTO

Previously at Nokia

–
Creator of Nokia and
Microsoft simulation system,
Head of Technology
Simulations



Markku Laitinen
COO

Previously at Nokia

–
Implementation of
Nokia and Microsoft
simulation system to
global product
creation.



Florian M. Thieringer
MD, DDS, MHBA Prof.
h.c. (Nic),
Maxillo-Facial Surgery



Risto Kontio
Maxillofacial Professor
Chief Physician



Gonçalo Barreto
Scientific Advisor,
Researcher
Ph.D. in Orthopedics



Alessio Bernasconi
MD, FEBOT
Orthopedic and Trauma
Surgeon



Jari Salo
Orthopedics Professor
Chief Physician



Marko Mykkänen
Orthopedics Surgeon
Foot and Ankle

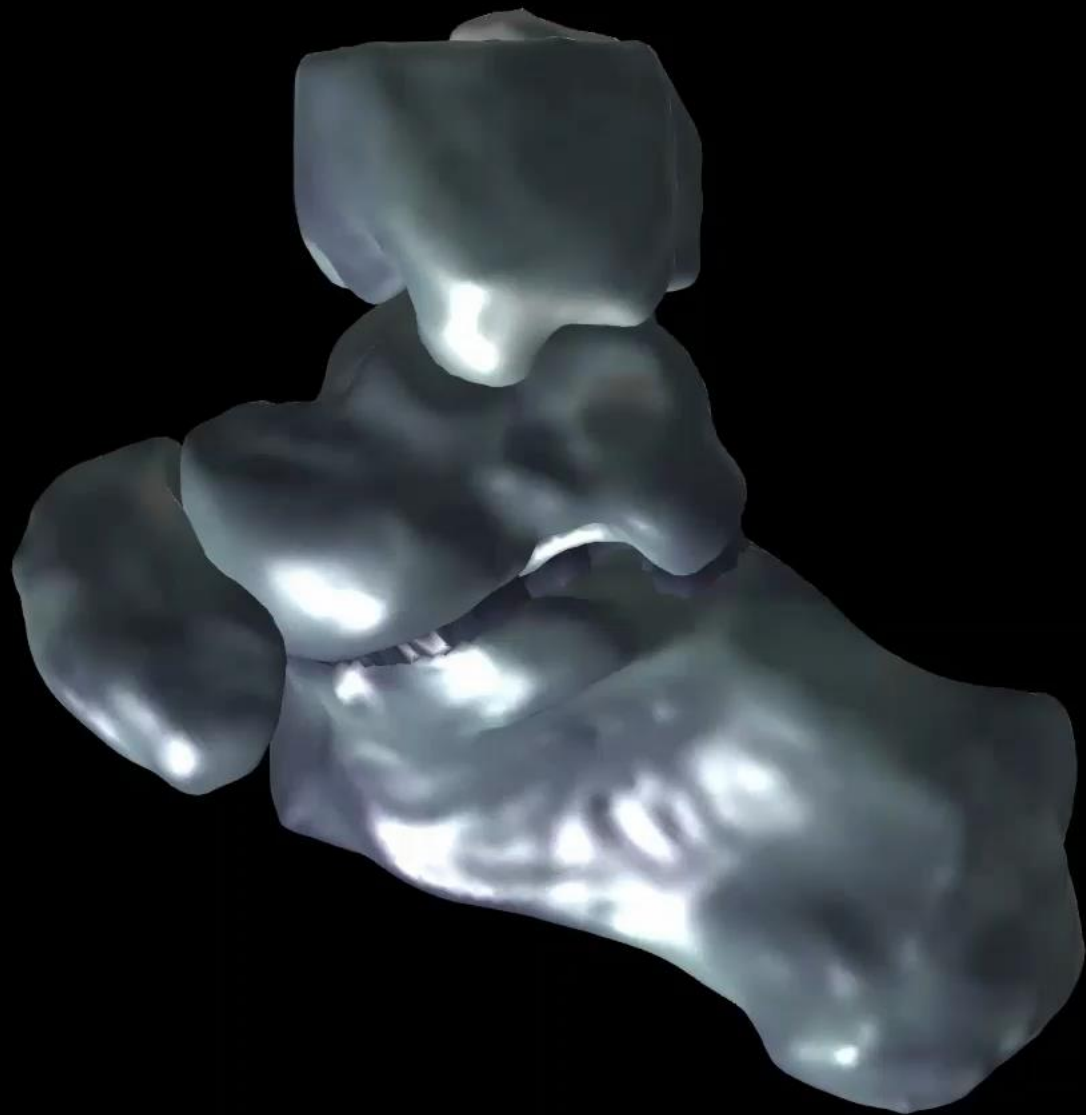


Dr François Lintz
MD, MS, FEBOT,
Senior Consultant Orthopedic
Surgeon



Eero Waris
Orthopedics Surgeon
Upper Extremity, Ass Prof.,
Chief Physician

DISI^OR
a n a l y t i c s



First product applications releases 2020

TECHNOLOGY SCALABLE OVER ANATOMIES

Bonelogic CMF Orbital CE I

Automatically analysed shape and size of fracture with virtual reconstruction of orbit

High quality 3D models with a design tool for user defined Patient Specific Implantation

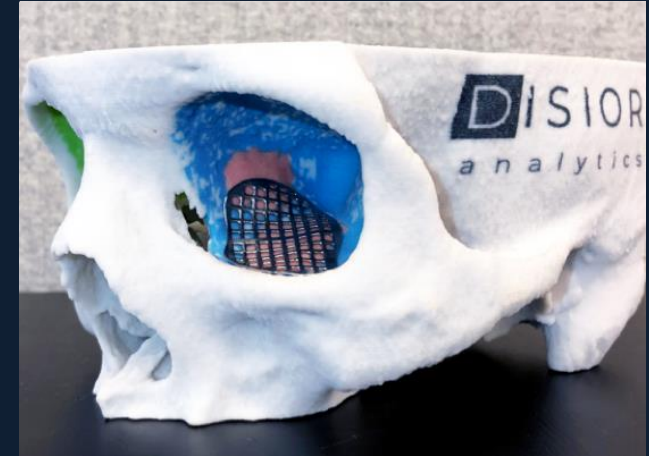
Bonelogic Ortho Foot and Ankle CE IIb

Automatically analysed anatomy and radiographic parameters

Excellent applicability for various malformation diagnoses of hindfoot and forefoot

Next anatomical area: Hand and Wrist

Maxillofacial: 3D analysis is already mainstream due to aesthetic reasons

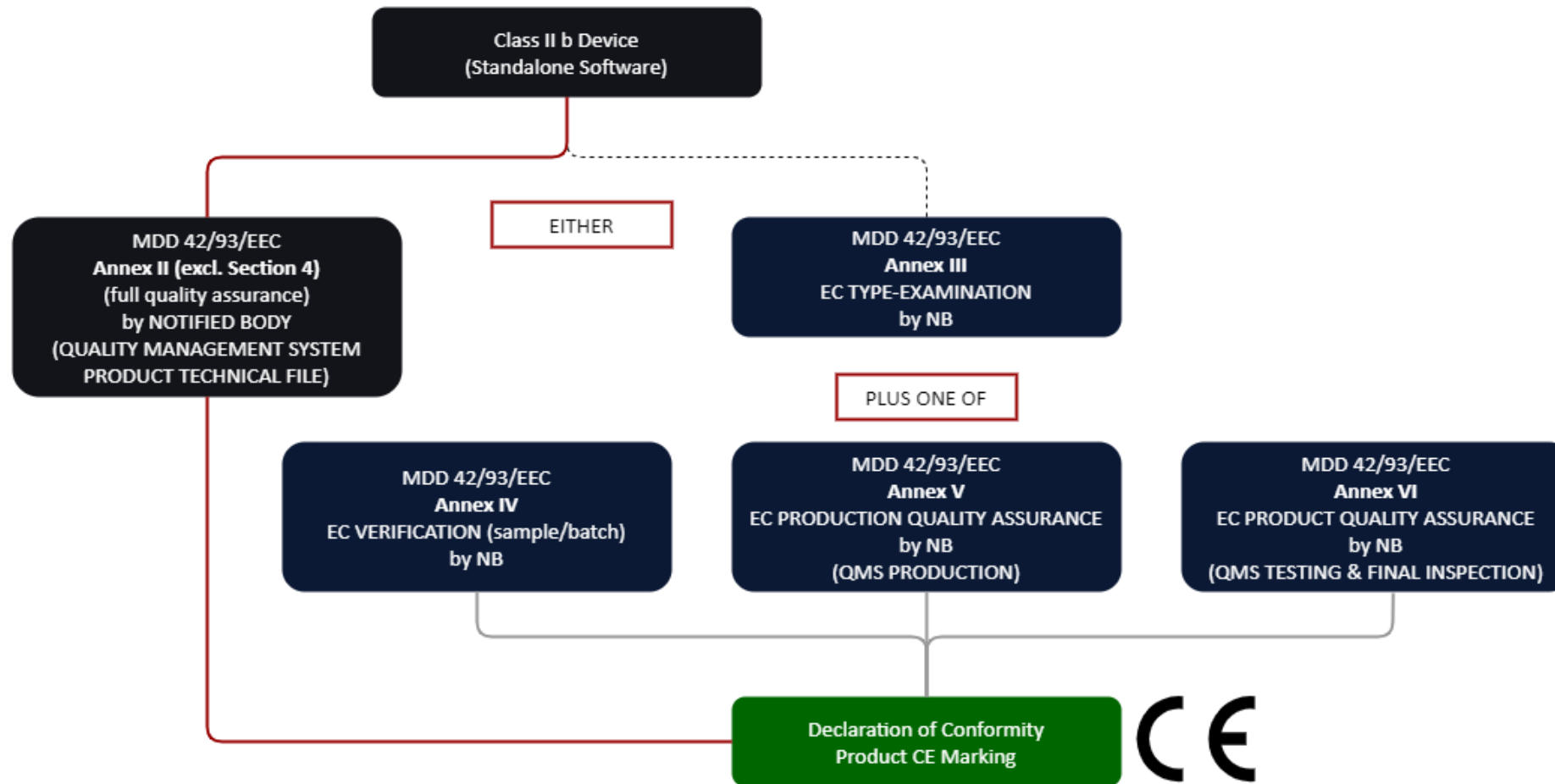


Foot and Ankle: 3D analysis is emerging due to complexity of system and need to restore biomechanics



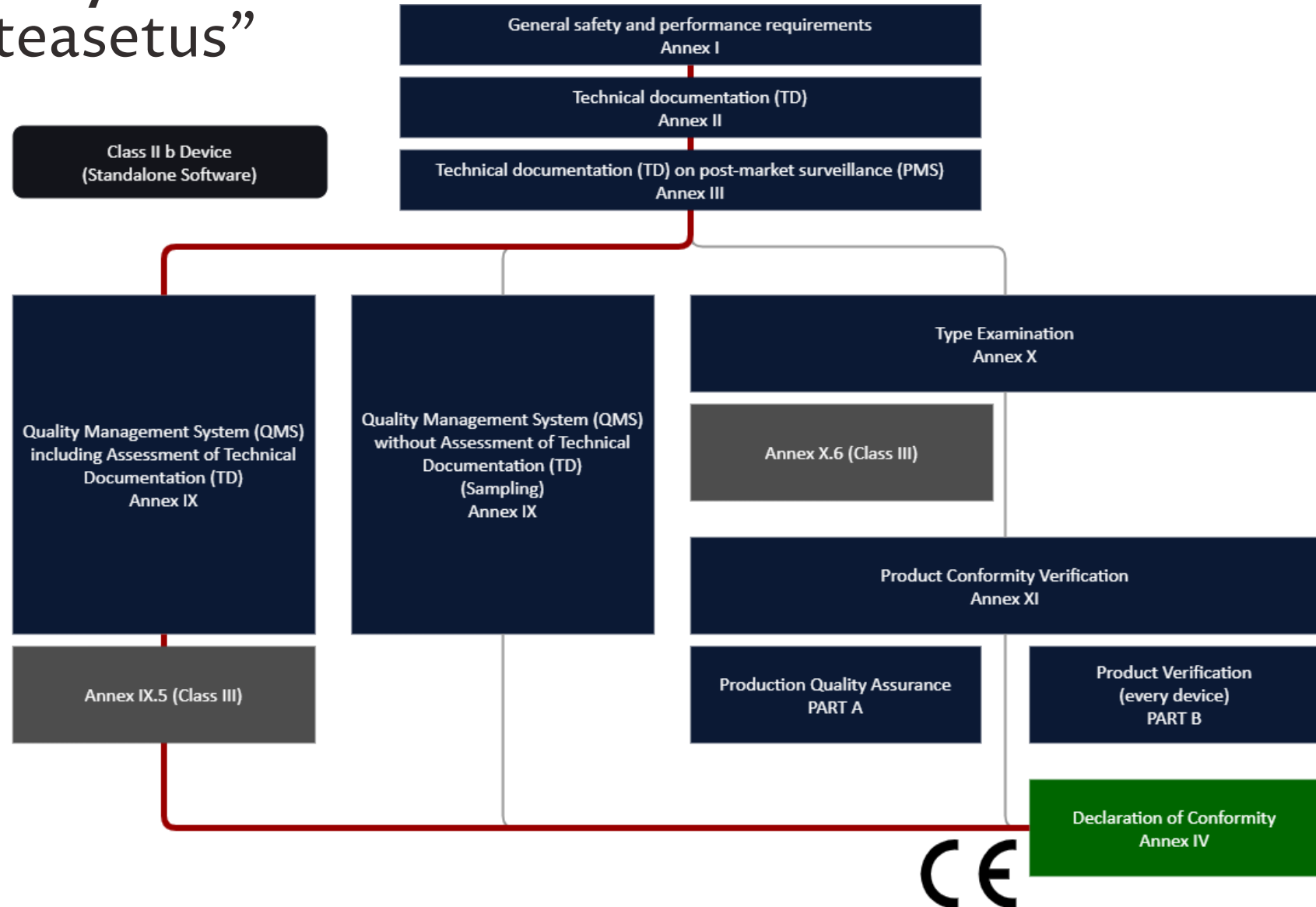
Conformity route MDD

“Lääkintälaitedirektiivi”



Conformity route MDR

“Lääkintälaitteasetus”



Full Quality Assurance Route

Full Quality Assurance

- Notified body audit Quality Management System (EN ISO 13485)
- Notified body assess technical documents (Planning-, testing, clinical evaluation)
- Company collects actively post-market & clinical information

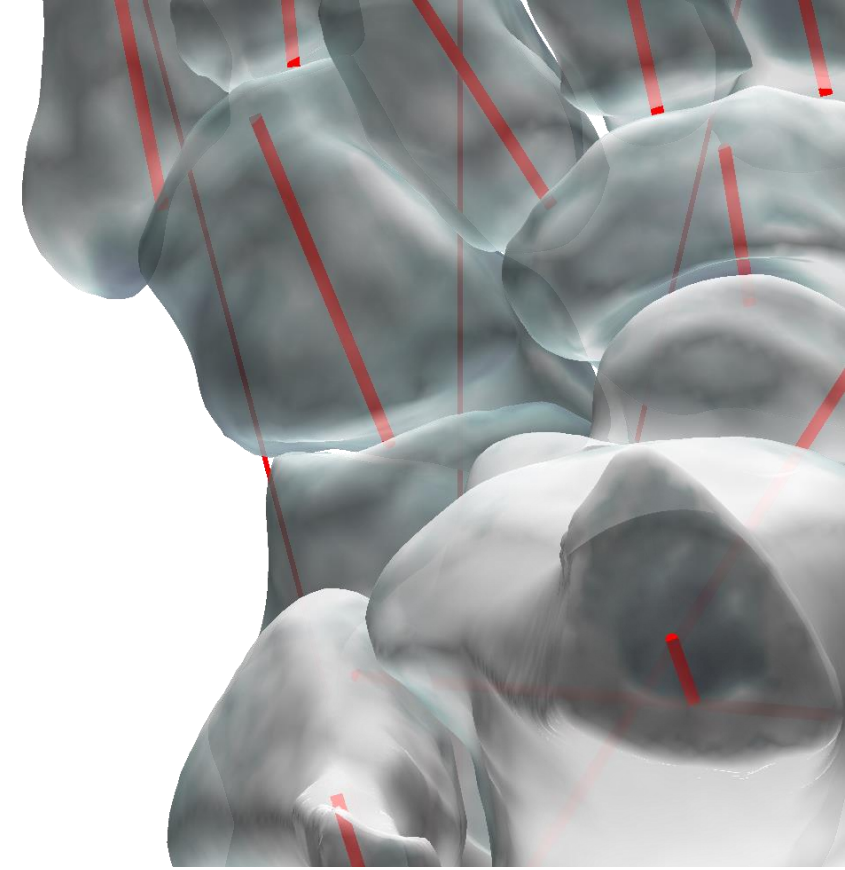
Calendar Time

- Quotation, 1-6 months
- QMS Pre-audit, Audit and corrections, Technical documents assurance, external assessment of clinical evaluation (ulkopuolinen) and reporting 12-15 months

Total approx. 2 years

What We Have Learned

1. Getting started, Planning
2. Quality Management System
3. Funding, Business Finland & VCs
4. Medical Devices vs. Digital Health
5. Culture
6. Are you really sure you want to do this...?



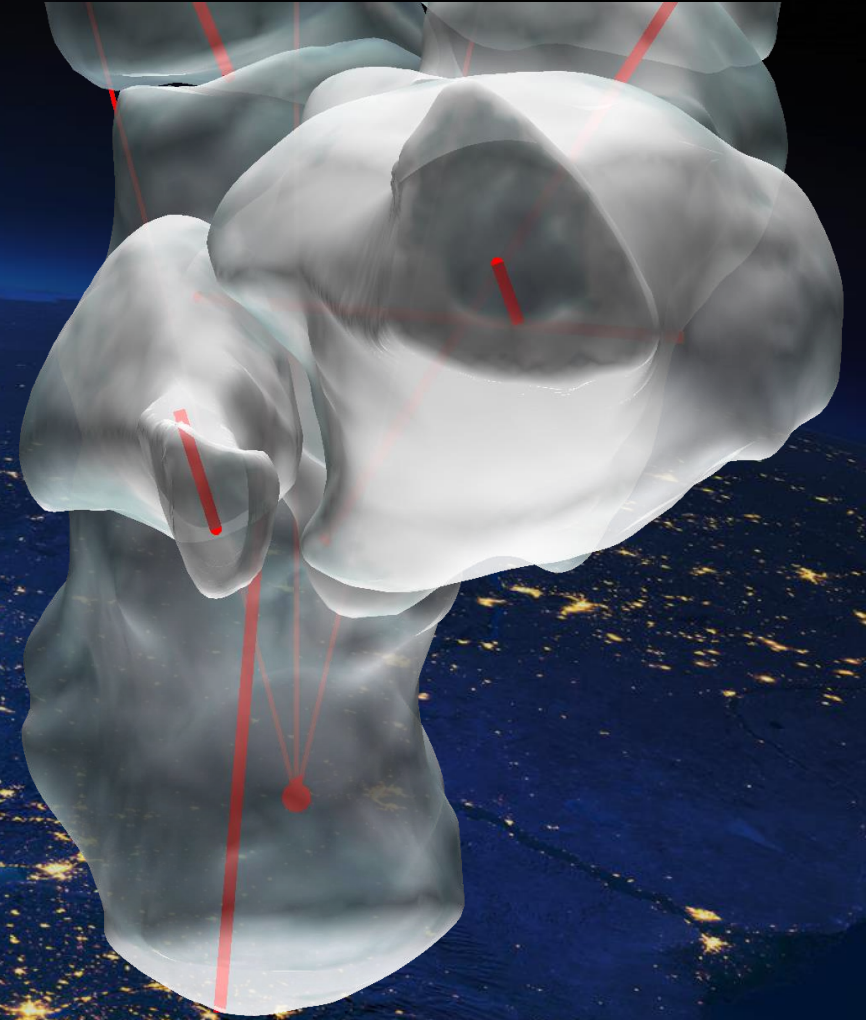
EVERYONE INVOLVED SHOULD BENEFIT!



Making Medical Imaging Intelligent

THANK YOU!

LET'S MAKE IT!





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