NORE (Network of Orthopaedic Registries of Europe) an EFORT standing committee
NIMAC symposium

Engaging with the new EU regulatory landscape for medical devices.

Challenges and opportunities

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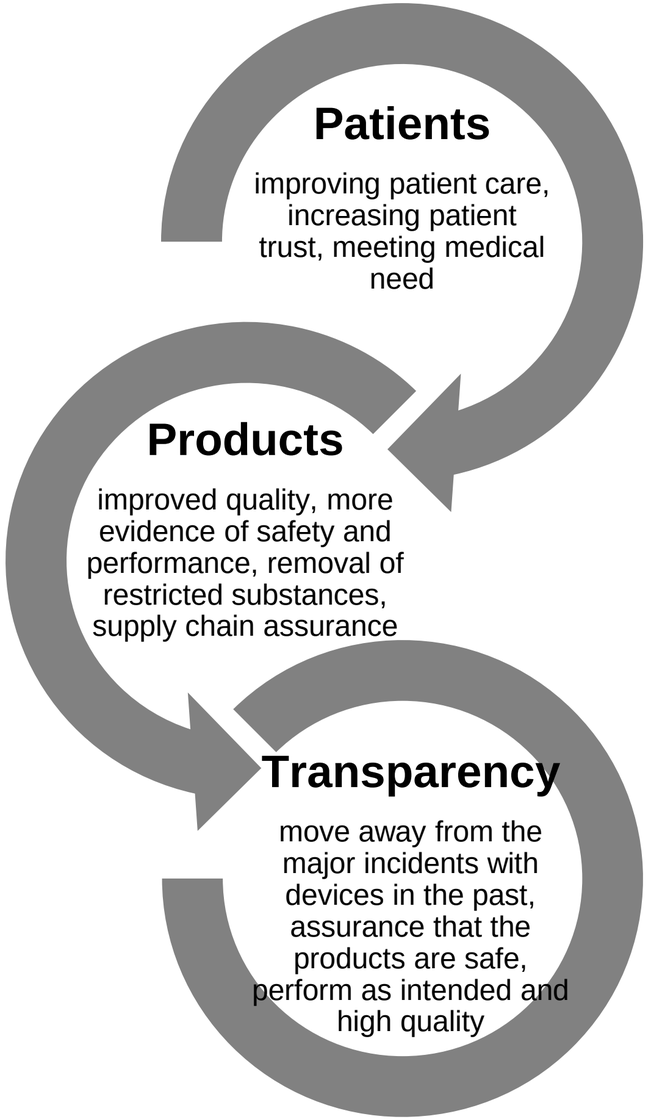
Session 3: **What to do next, quality and safety for future patients**

The future from the eyes of a surgeon who is also connected to a manufacturer

When therapeutic choices include implantable devices what primarily count is:

- Safety of the implant
- Performance to be evaluated both as therapeutic efficacy and efficiency
- Degree of patient satisfaction

Medical Device Regulations (MDR) > Law



MDR aims to…

- Significant changes to product introduction
- Risk reduction and monitoring via premarket scrutiny and post market surveillance
- Increased evidence (premarket, clinical and technical) for approvals
- To improve quality and safety of medical devices for patients
- It is closely aligned with device effectiveness/performance
- To increase in market safety and monitoring
- Monitoring and compliance through product lifetime
- Make public health information accessible

MDR Context

Under the **MDD**:
manufacturer could certify met technical requirements and place on the market

Under the **MDR**: manufacturers MUST provide evidence on clinical benefit to patients

Rules to be fulfilled in order to CE mark a medical device and make it available on the CE-recognizing markets

Stands alone, not following FDA or other bodies

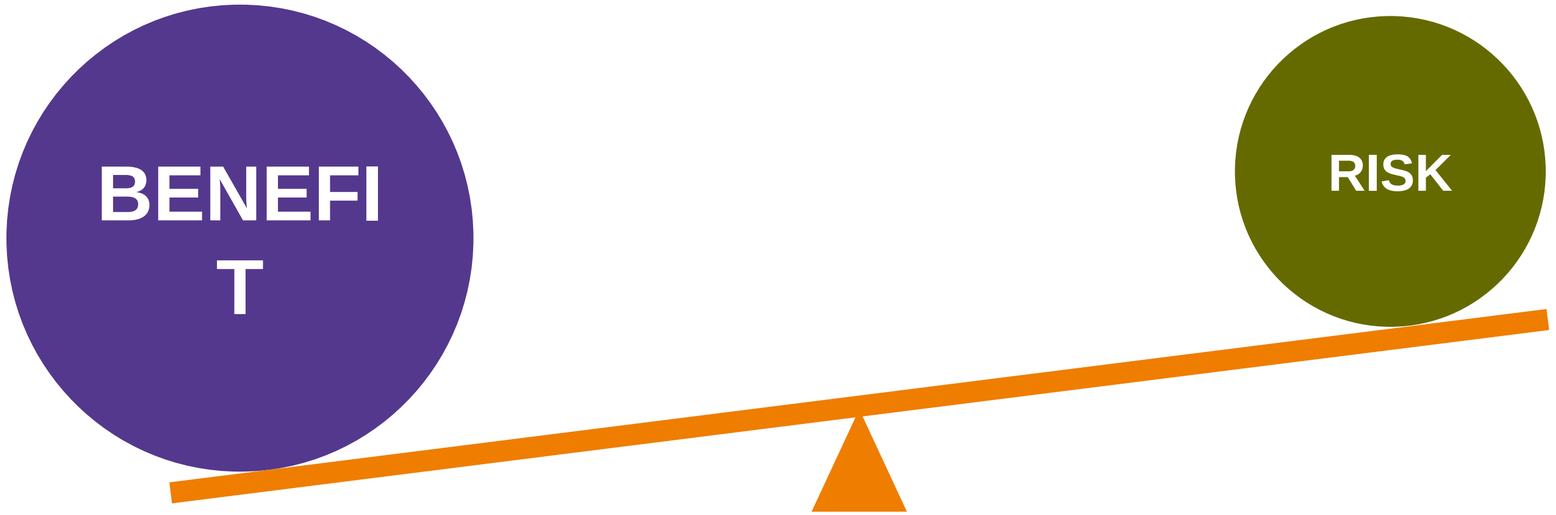
Risk Benefit Assessment to the patient

Manufacturers must:

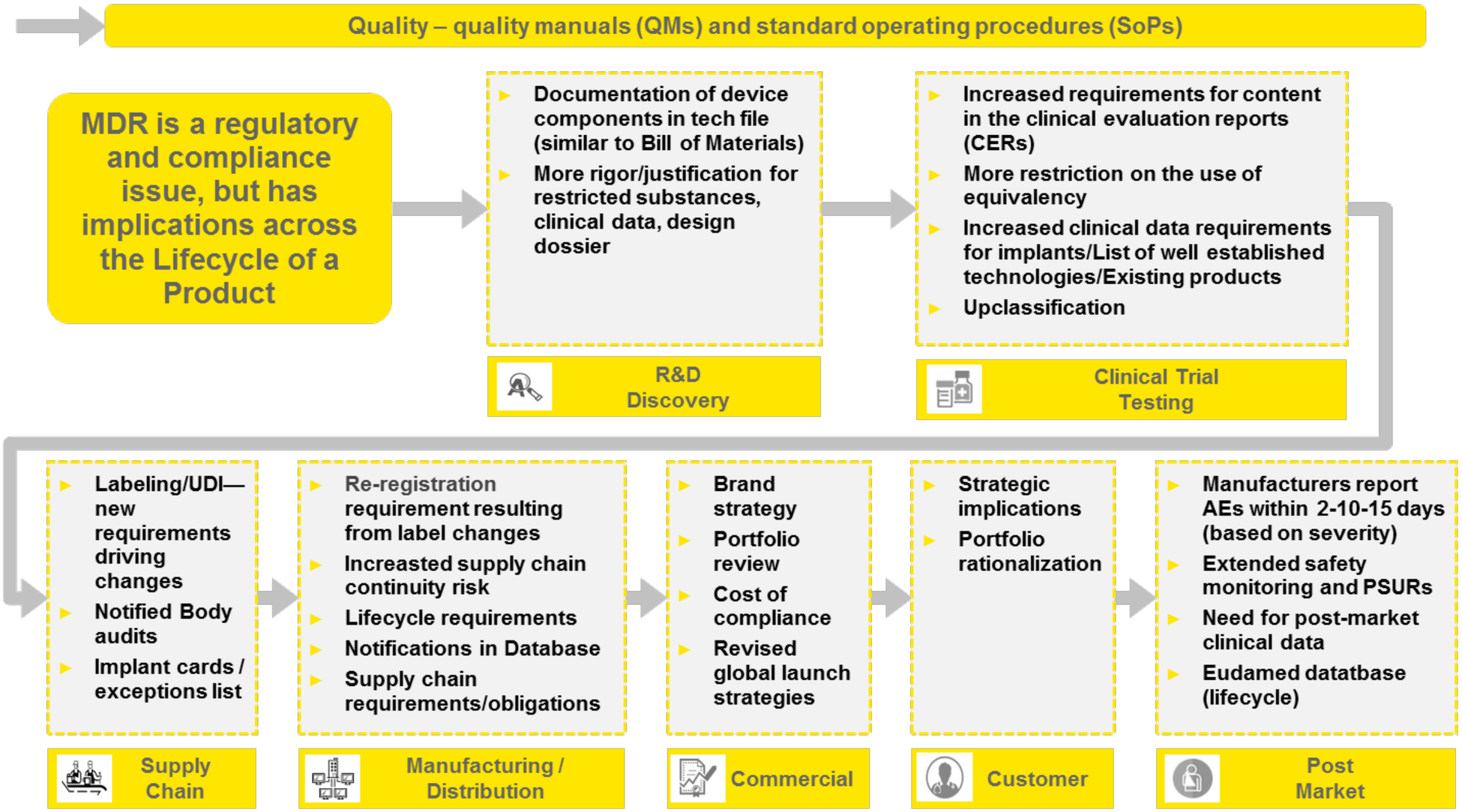
Prove reduced patient risk as much as possible pre-market

Continuously assess the risks and anticipated benefits post launch throughout product lifecycle

Provide overall evaluation of acceptability of the benefit/risk profile
(incl different patient populations)



The MDR has Implications Across the Whole Product Lifecycle



Actual main sources for Performance demonstration

Clinical investigations (including RCTs) and PMCFUs

Registries (when available)

Actual main sources for Safety demonstration

Clinical Investigations (including RCTs) and PMCFUs

Registries (when available)

All PMS data including complaints

Sustainability

ADEs and SADEs detection some Registries are probably tailored form a numeric point of view to provide meaningful informations for relatively common AEs (1 to 0.5% occurrence rate)

Expected incidence of adverse events	1 event	2 events	3 events
1 in 100	300	480	650
1 in 200	600	960	1300
1 in 1100	3000	4800	6500
1 in 2000	6000	9600	13000
1 in 10000	30000	48000	65000

Source: *Safety requirements for the first use of new drugs and diagnostic agents in man.* Geneva CIOMS(WHO) 1983

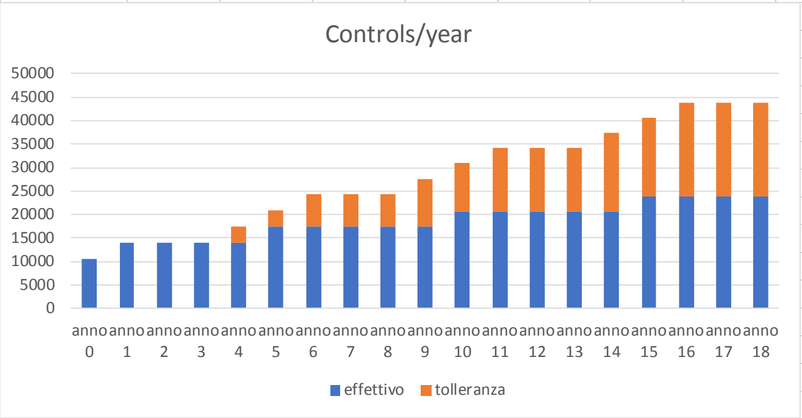
What about patient satisfaction?

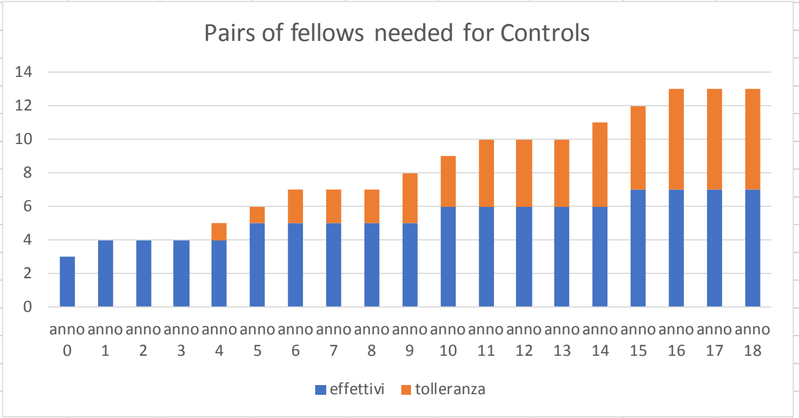
Registries will not limit to record revisions only but start to introduce regular scheduled FUs to capture clinical outcome and PROMs?

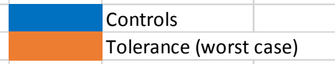
Sustainability

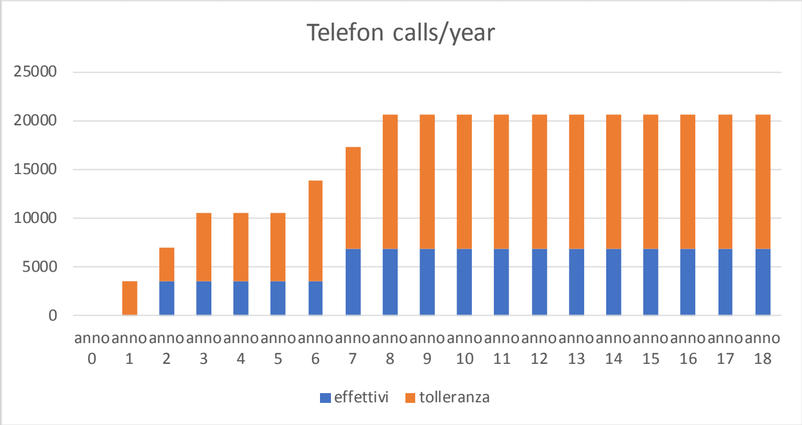
patients/yr	3500															
	yr 0	yr 1	yr 2	yr 3	yr 4	yr 5	yr 6	yr 7	yr 8	yr 9	yr 10	yr 11	yr 12	yr 13	yr 14	yr 15
censoring						0.02		0.03			0.05					0.1
f.u. in loco	xxx	x			(x)	x	(x)			(x)	x	(x)			(x)	x
f.u. teleffon		(x)	x	(x)			(x)	x	(x)							

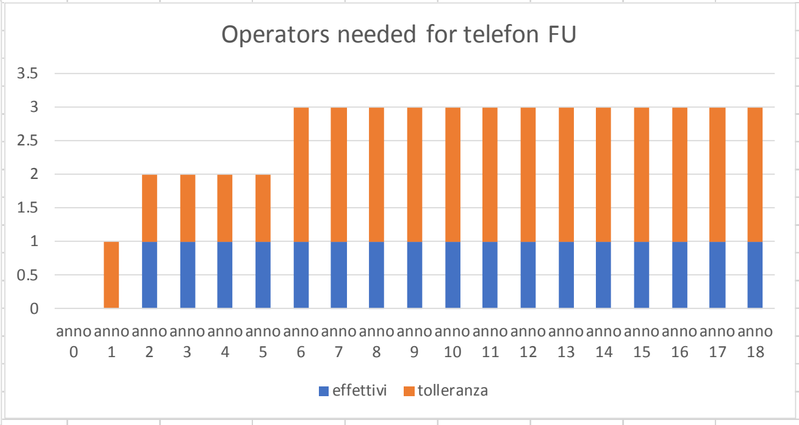
	IN LOCO	TELEFON
controls/hour	5	5
hours/day	3	8
days/week	5	5
weeks/year	50	50











Patient Reported Outcome Measurements

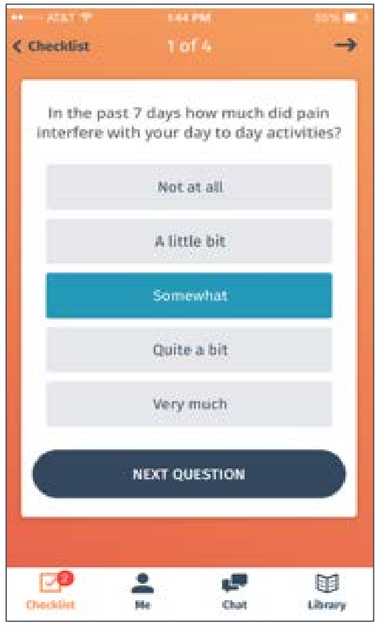
- A Patient-Reported Outcome Measurement (PROM) is a health outcome directly reported by the patient who experiences it.

- PROMs measure a patient's health status or health related quality of life at a single point in time.

- Traditional PROMs may be over 40 questions long. A reliable system, customized to the patient that uses less questions has been developed, validated and is available

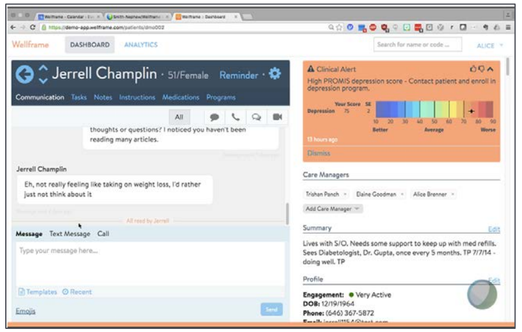
innovation in PROMs for TKA patients

PROMs collected using an electronic tool (smartphone) and sent to the surgeon's computer…



App

Built using PROMIS knowledge



Administered using Computer Adaptive Tests (CATs)

- Physical Function CAT
- Pain Behaviour CAT
- Pain Interference CAT
- Depression CAT

What is the Patient-Reported Outcomes Measurement Information System®? (PROMIS)

- Developed and evaluated using state-of-the science psychometric methods funded by the NIH.
- Measures used to evaluate and monitor physical, mental, and social health.
- Relevant across all conditions – they are not disease specific.
- Scores on one metric – gives a score between 20 and 80.

COMPUTER ADAPTIVE TESTS (CATs) on the app

- Individually tailored electronic questionnaires
- Focused on a single domain
- Next item administered from item bank depends on previous answers
- Typically 5-7 questions.

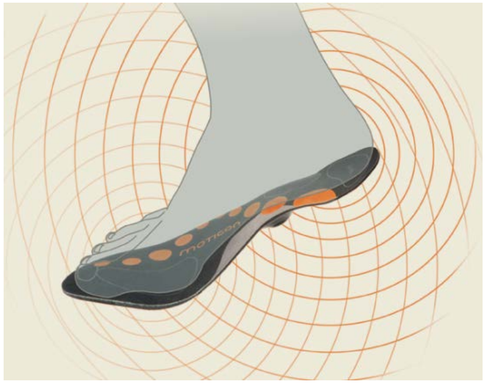
Think of it as intelligent questioning…

- If this person says they cannot walk 1 mile without pain, there is no need to ask any questions related to sport etc.

The focus is on calibrating just how bad their pain interference is…

Compare this to traditional PROMs where <u>every</u> question must be asked…

Moticon's OpenGo



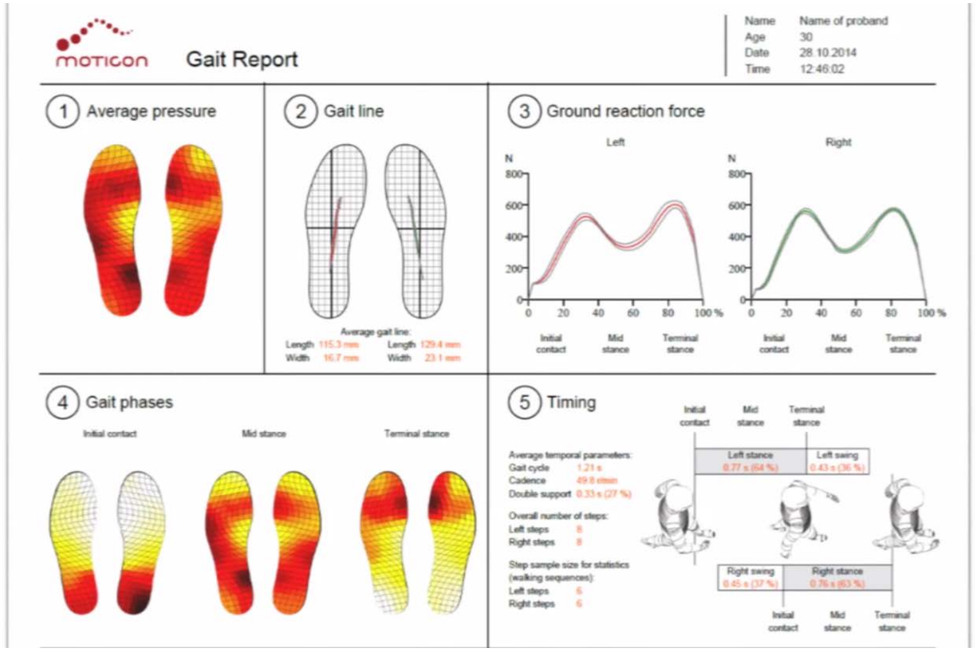
3 component categories

- SENSOR INSOLES
- SOFTWARE
- ACCESSORIES

Operation overview 1 2 3

LIVE	Data streamed in real time
RECORDING	Data stored for later bluetooth transmission
SLEEP	Energy conservation when not in use

What does the sensor insole measure?

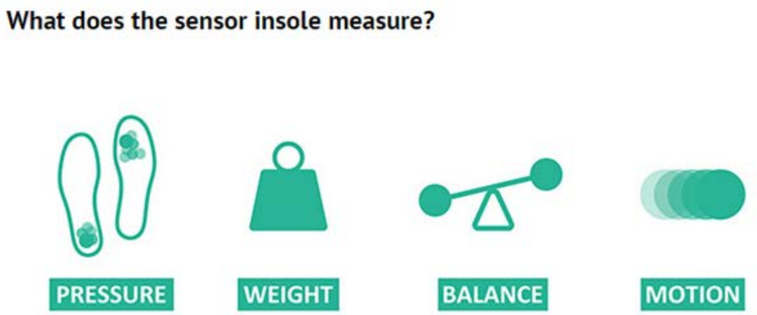


- Each insole contains 14 sensors
  - 13 capacitive pressure sensors
  - 3 accelerometer

http://www.moticon.de/products/physio-pro-sports#physio-pro-sports-overview

Sensor overview

Each sensor insole contains 13 capacitive pressure sensing pads and a 3D accelerometer for measuring motion.
The sensor data is processed in the embedded microsystem. From this raw data, a variety of essential gait and motion parameters are computed.



http://moticon.de/products/science-research

Conclusions: how may the future look like?

- No «fit for all» single solution
- No need to duplicate data with a different methodological approach if data already exist
- Patients' own appreciation unavoidable
- Take into account overall sustainability (financial and human resources) of the projects
- Exploit new technological approaches to generate evidence
- Evidence will possibly be generated by a well balanced mix of different approaches each conceived and properly weighted in the Critical Appraisal Process