Postmarket surveillance & (Quality) Registries

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Dilemma: RCT patients ⇔ **Your Practice**

REAL World Data = **Registry data**

National Joint Registry
www.njrcentre.org.uk
Working for patients, driving forward quality

>1.5 million

AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

>720.000

DATA about 4 million TH TK procedures

LROI
Dutch Arthroplasty Register

>630.000

NARA
Nordic Arthroplasty Register Association

>730.000

Dutch Arthroplasty Register

LROI

Aantal registraties op dit moment

LROI

Totaal **600.305**	Heup **332.394**	Knie **256.488**	Enkel **495**
Schouder **10.131**	Elleboog **636**	Pols **50**	Vinger/duim **111**

https://www.lroi.nl/kalender/2018/01#cal20

15 JAN

MA 15 JAN 00:00-23:59

LEES MEER →

Deadline indienen abstracts ISAR congres (IJsland)

Revision TKA PS CR

LROI

men

11.6% (95%-CI: 10.2-13.3)

6.6% (95%-CI: 5.7-7.6)

Legend (men):
- PS Age <60 years
- PS Age 60-69 years
- PS Age 70+ years
- CR Age <60 years
- CR Age 60-69 years
- CR Age 70+ years

Y-axis: Cumulative revision rate (%) in **males**
X-axis: Years after primary TKA

females

Legend (females):
- PS Age <60 years
- PS Age 60-69 years
- PS Age 70+ years
- CR Age <60 years
- CR Age 60-69 years
- CR Age 70+ years

Y-axis: Cumulative revision rate (%) in **females**
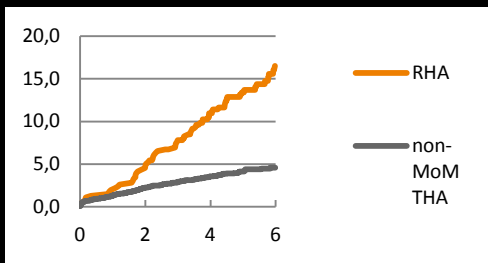X-axis: Years after primary TKA

More than 95% completeness of reported procedures in the population-based Dutch Arthroplasty Register

External validation of 311,890 procedures

Liza N VAN STEENBERGEN[1], Geke A W DENISSEN[1], Anneke SPOOREN[1], Stephanie M VAN ROODEN[2], Frank J VAN OOSTERHOUT [3], Jan W MORRENHOF [4], and Rob G H H NELISSEN[5]

Which Implant ?

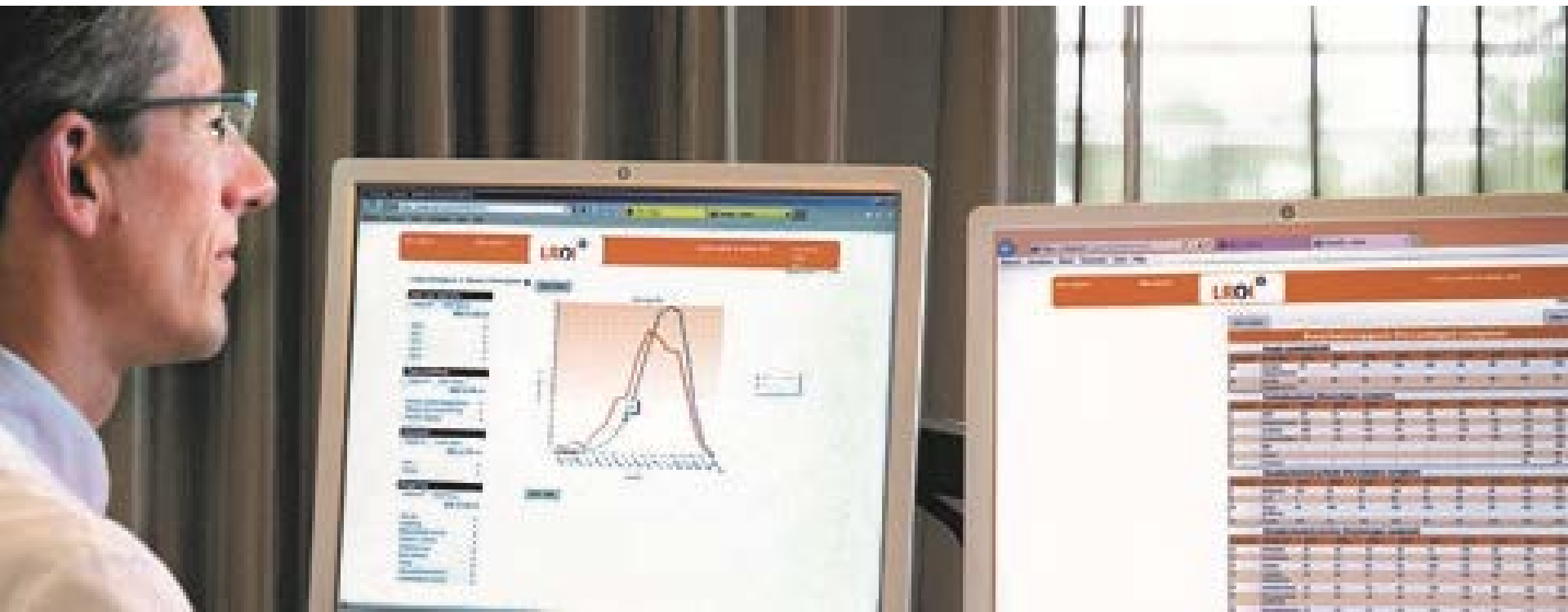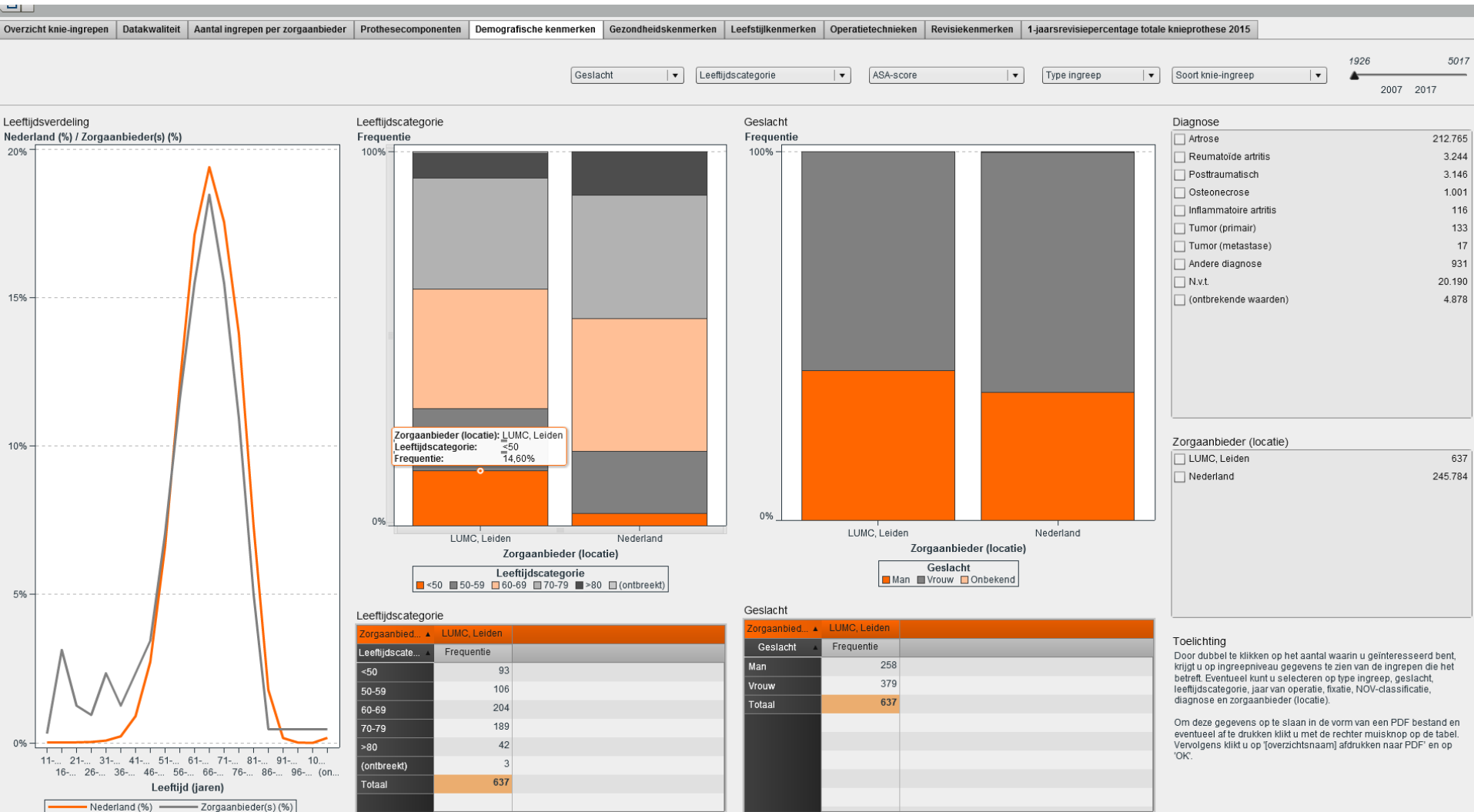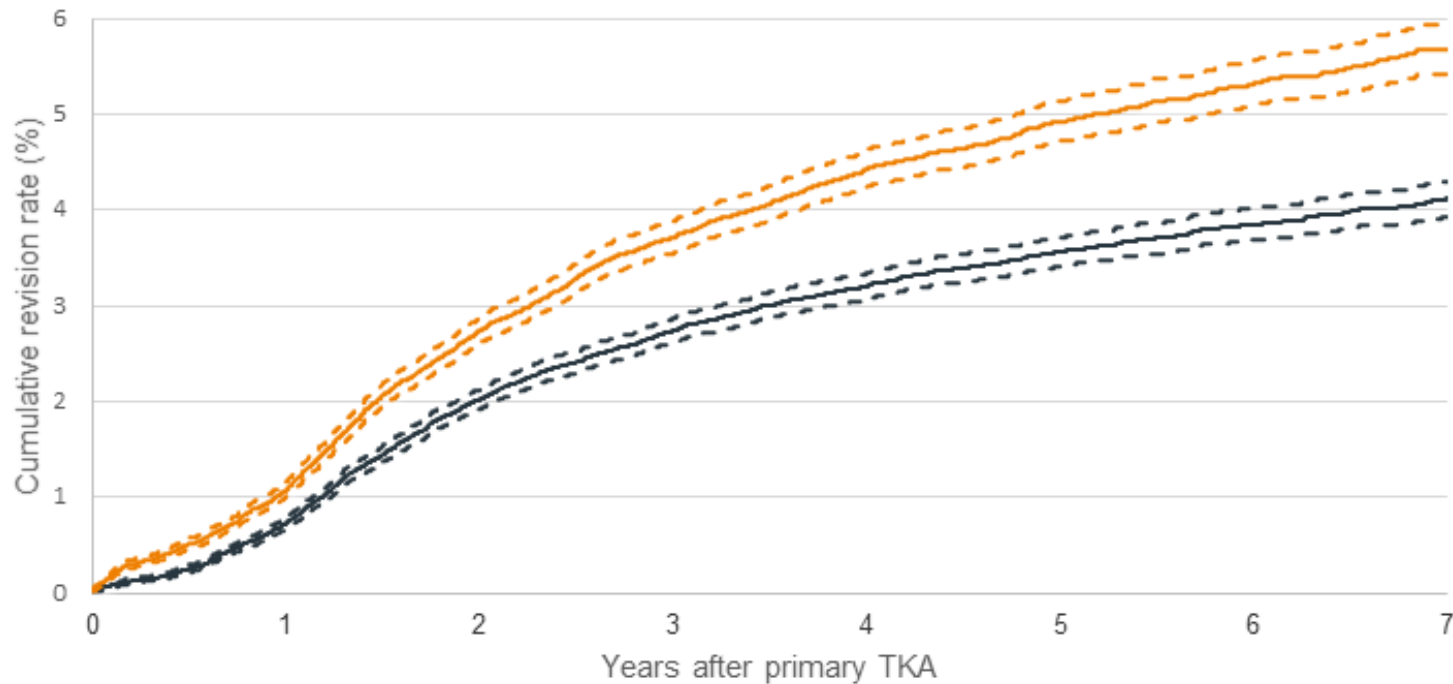|	RHA
	non-MoM THA
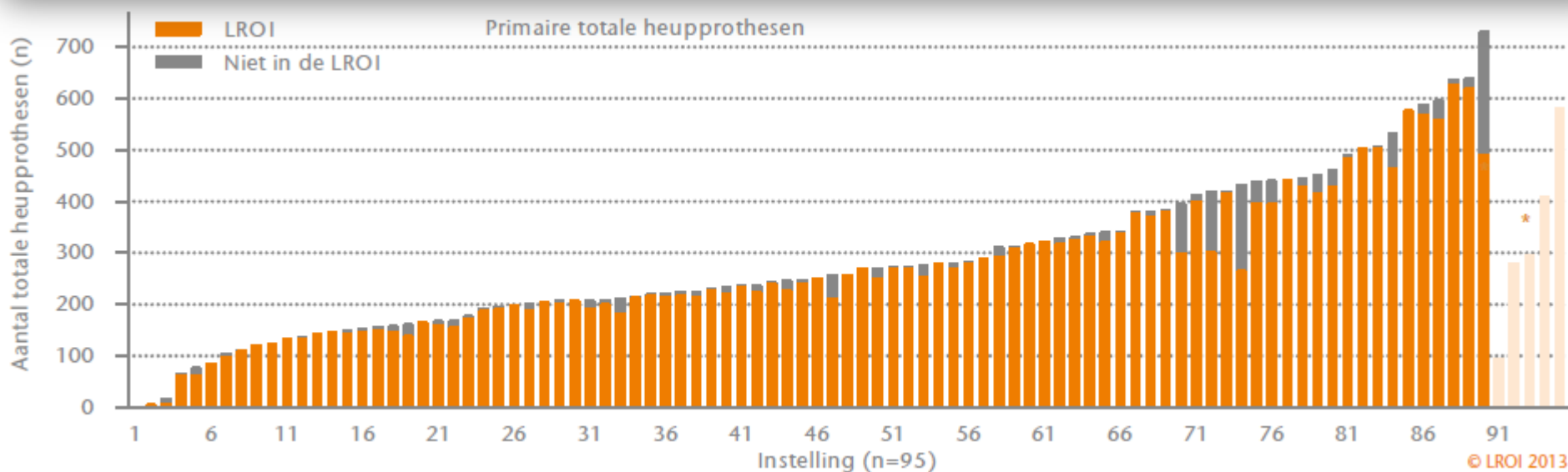
Implant register + **Quality register**

Real-time *Patient specific Reflection*

preop Casemix LUMC <-> NL

Bechmarking
Own Practice vs Netherlands

LROI®
Dutch Arthroplasty Register

NOV 1 A

- > 90% survival @ 10 yrs in at least 500 cases

NOV 1 B

- > 95% survival @ 5 yrs in at least 500 cases

NOV 2

- no data available: informed consent + prospective study

*NOV classes based on data validated Registries (> 90% completeness)*

2. Australian National Joint Replacement Registry
3. National Joint Registry for England, Wales and N. Ireland
4. Danish Hip Arthroplasty Register
5. ODEP Orthopaedic Data Evaluation Panel, U.K.

NOV 1A classificatie:

NOV 1A	10 jaar resultaat	01-10-2016	
Gecementeerde knieprothesen – Posterior Stabilized		Gecementeerde knieprothesen – Cruciate Retaining	
Merk	Model	Merk	Model
Smith & Nephew	Genesis II CoCr	Corin	Rotaglide
ZimmerBiomet	AGC V2	DePuy	LCS Complete
ZimmerBiomet	Nexgen	DePuy	PFC Sigma
		Smith & Nephew	Genesis II CoCr
		Smith & Nephew	Genesis II Oxinium
		ZimmerBiomet	AGC V2
		ZimmerBiomet	Nexgen
		ZimmerBiomet	Vanguard Complete Knee
Gecementeerde knieprothesen – Cruciate sacrificing			
Merk	Model		
MatOrtho	MRK Fixed Bearing		

NOV 1A	10 jaar resultaat	01-10-2016	
Ongecementeerde knieprothesen		Ongecementeerde knieprothesen – Cruciate Retaining	
Merk	Model	Merk	Model
DePuy	LCS complete (porocoat)	ZimmerBiomet	Nexgen
ZimmerBiomet	ROCC		

LROI
Dutch Arthroplasty Register

Quality Acetabular component
1A: 90% survival at 10yr; 1B 95% survival at 5yrs; 2: no data

Legend:
- Category 2
- category 1A / 1B
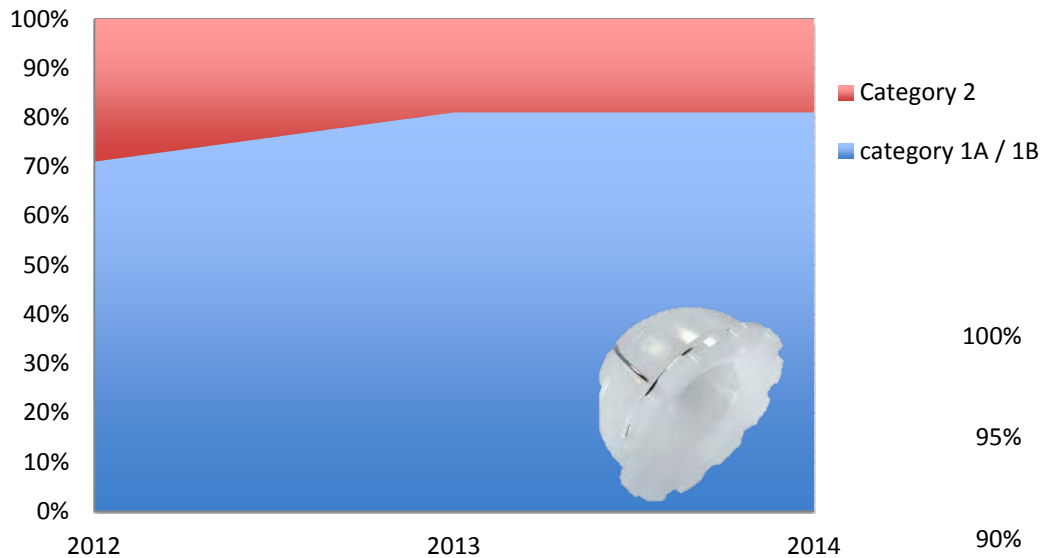
Quality Femoral component
1A: 90% survival at 10yr; 1B 95% survival at 5yrs; 2: no data

Legend:
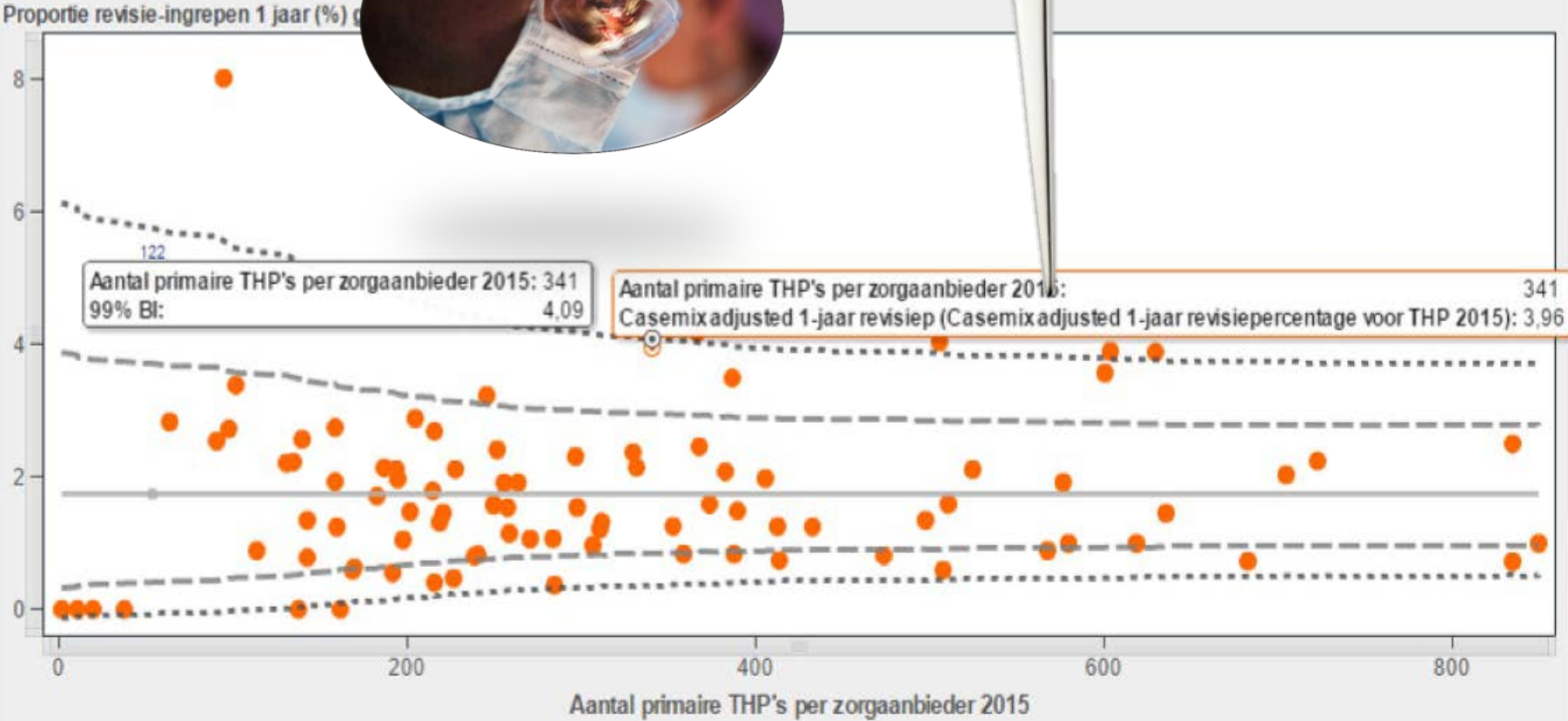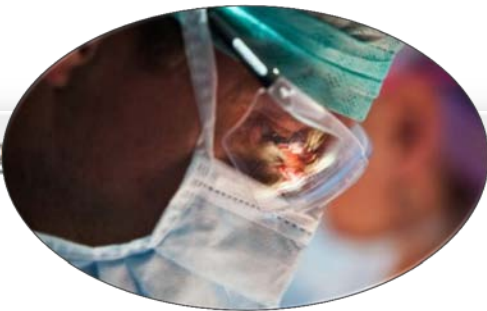- Category 2
- category 1A / 1B
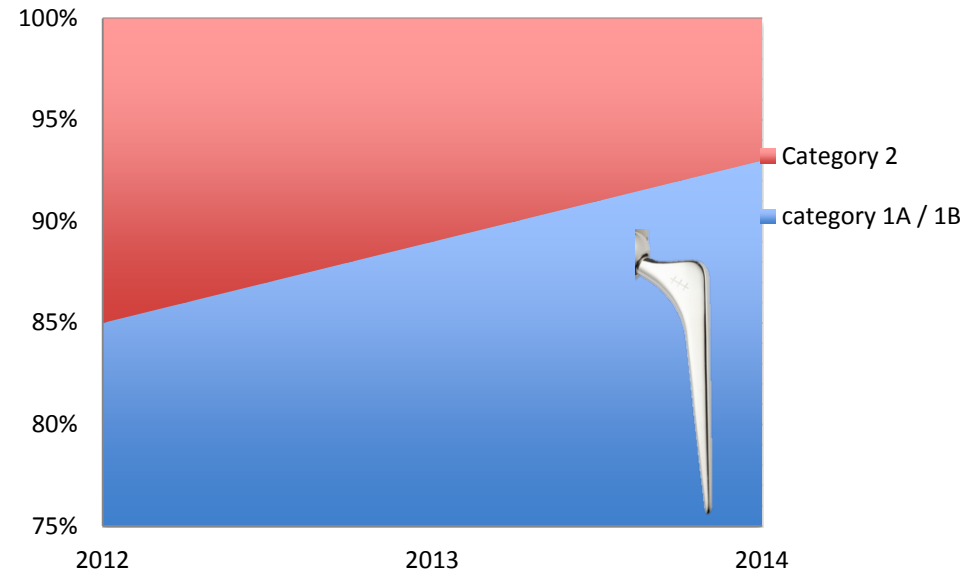
stepwise escalation**: "Healthy Confidence,** *but* **Accountable"**

NOV

Netherlands Orthopaedic Association

Phase I: Detection Outliers

LROI
Dutch Arthroplasty Register

Proportie revisie-ingrepen 1 jaar (%) g

122

Aantal primaire THP's per zorgaanbieder 2015: 341
99% BI: 4,09

Aantal primaire THP's per zorgaanbieder 2015:   341
Casemix adjusted 1-jaar revisiep (Casemix adjusted 1-jaar revisiepercentage voor THP 2015): 3,96

Aantal primaire THP's per zorgaanbieder 2015

1-'Gecorrigeerd voor geslacht, leeftijd, ASA score, diagnose, BMI, Charnley score en roken.'

Phase II.1 Implants:
Analysis + Actionplan

NOV

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Phase I: Outlier detection

Anomisation disclosed of type of Implant by LROI + analysis
International Registries

Industry feedback on Findings **+** Request why Implant is outlier and
Why Safe to use

Scientific Commitee LROI recommends escalation Phase III based on
- Evidence Outlier
- Report Industry

Phase III Ouliers

Phase II.2 **Surgeon Group**:
Analysis Outliers + Actionplan

Netherlands Orthopaedic Association

Phase I: Outlier detection
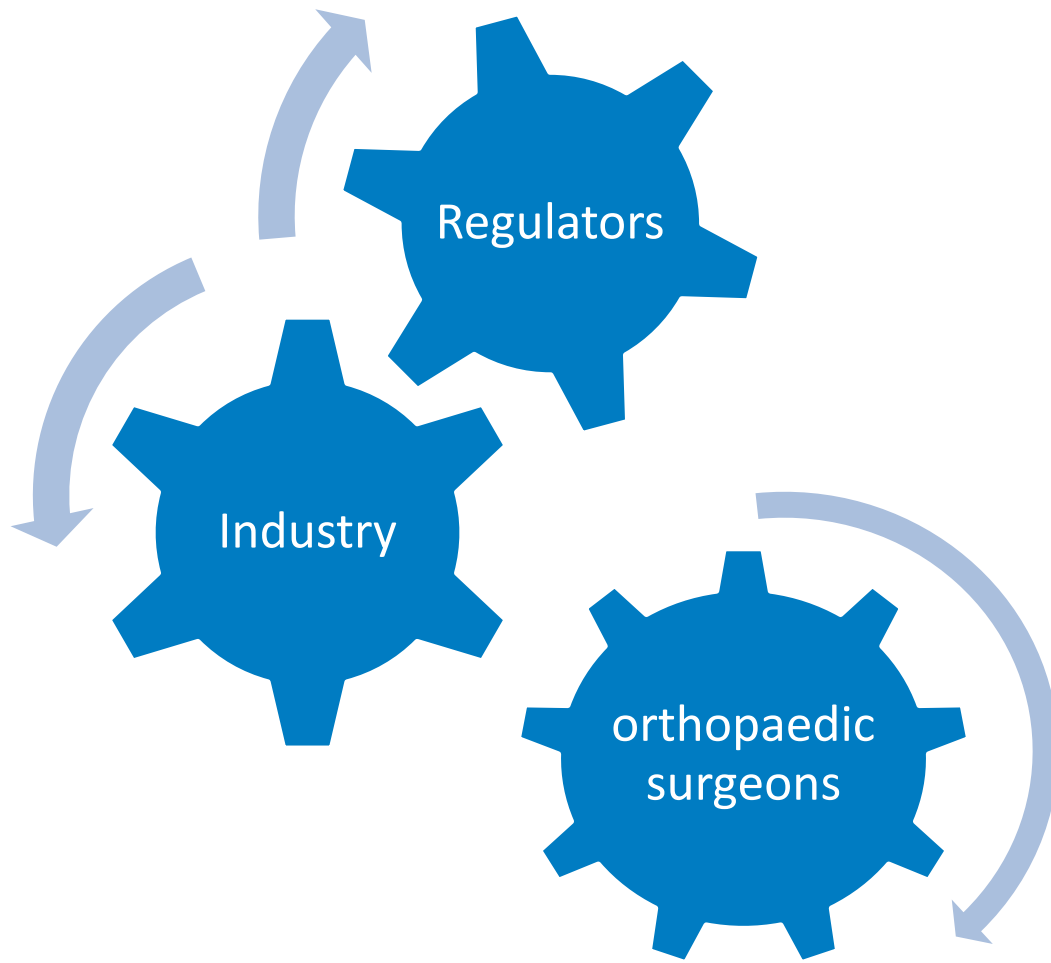
(anominised) Outliers discussed by Quality commitee NOV

Anominisation disclosed by Quality subcommitee NOV

Quality subcommitee reports to **Surgeon's Group** *and* Requests:
- reasons Outliers
- which actions

If
- Surgeon Group is Outlier 2nd time   *and*
- Outlier cannot be explained   *and*
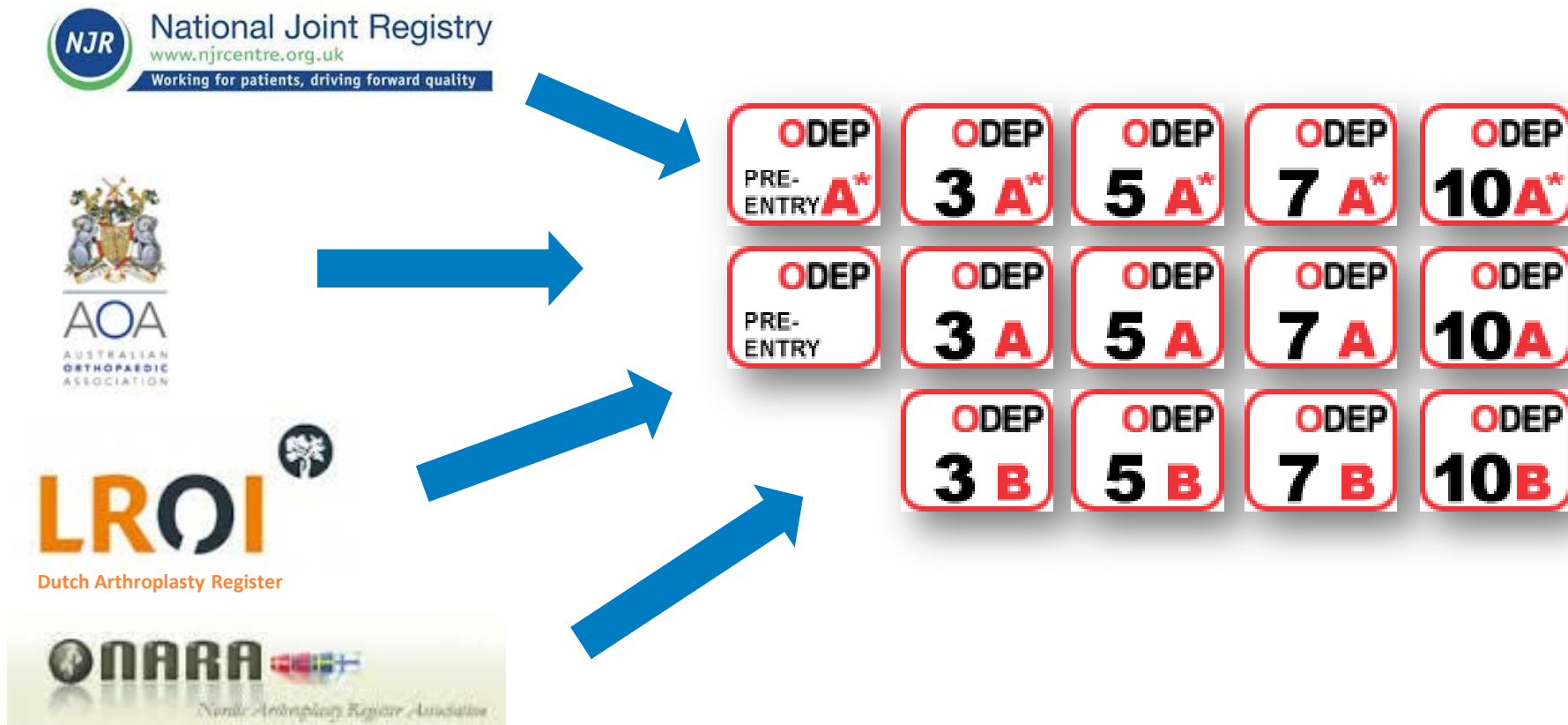- Outlier = high clinical impact

     => Phase III

It is not the strongest of the species that survives, nor the most intelligent.
It is the one that is most adaptable to change.

Charles Darwin