The Life of a TJR
The stages of regulating and monitoring a total joint replacement

Now and the future

nore
Network of Orthopaedic Registries of Europe

Amie Smirthwaite

&

Keith Tucker

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WHAT WE ARE DISCUSSING TODAY…….

WHAT WILL A MANUFACTURER HAVE TO DO IN THE FUTURE TO OBTAIN A

CE MARK?

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ODEP
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DECLARATION OF INTERESTS
KEITH TUCKER

Consultant Orthopaedic Surgeon. President BHS 2007-8

Chair Beyond Compliance advisory group and ODEP

Past Member NJR Steering Committee.
Member NJR Implant performance committee,

In the past I received monies from J&J for being **a co-designer of 4 hip replacement implants.**
All royalties were paid into a research fund

I hold stock in Accentus Medical
I do not receive any financial reward for NJR,MHRA BEYOND COMPLIANCE or ODEP work. My travel expenses are reimbursed.

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WHERE I STARTED

- BOA REPRESENTATIVE TO MDA 1986

- JUST AFTER CE MARKS WERE INTRODUCED
- MDA HAD JUST BECOME THE COMPETENT AUTHORITY

- WHAT ABOUT PMS I ASKED

- YOU WILL HAVE TO CHANGE EU LAW IF YOU WANT THAT!!

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WHY AM I HERE

- I AM A SURGEON AND HAVE SEEN THE RESULTS OF BAD IMPLANTS
- SURGEONS DO NOT WANT TO USE BAD IMPLANTS
- SURGEONS WANT TO BE SURE THAT THE REGULATIONS ARE THE BEST THEY CAN BE
- MANY SURGEONS ARE PREPARED TO HELP WITH THE INTRODUCTION OF NEW IMPLANTS
- MOST OF US ARE PASSIONATE ABOUT THESE ISSUES

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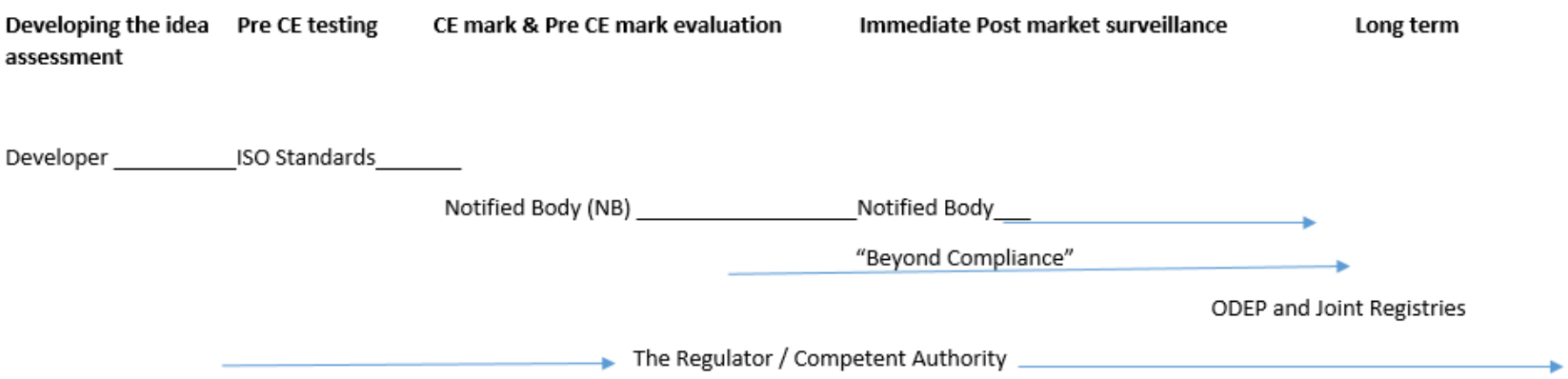
WHERE WE ARE

- POST CE
- POST MOVING TJRS FROM 2b to 3
- WE HAVE AN OPPORTUNITY OF GETTING IT RIGHT THIS TIME
- THE NEW REGULATIONS
- THERE ARE NOW > 2 MILLION TJRS INSERTED THROUGHOUT THE WORLD pa

THE LIFE OF A TJR



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A NEW JOINT REPLACEMENT

- THE THOUGHTS ARE PUT DOWN ON PAPER

- A MANUFACTURER IS INVOLVED
- ALL ASPECTS OF THE DESIGN ARE DISCUSSED
- EQUIVALENCES ARE LISTED

- ISO STANDARDS ARE OBSERVED

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A NEW JOINT REPLACEMENT
ISO STANDARDS

- INTERNATIONAL ORGANISATION FOR STANDARDIZATION
- www.**iso**.org/home.htm
- ISO creates documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.
- We've published 22041 International Standards, which you can buy from our members or the ISO Store.
- Bringing real and measurable benefits to almost every sector imagineable, standards underpin the technology that we rely on and ensure the quality that we expect.

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A NEW JOINT REPLACEMENT
ISO STANDARDS

- INTERNATIONAL ORGANISATION FOR STANDARDIZATION

AMIE…

- HOW GOOD ARE THEY FOR JOINT REPLACEMENT?

- ARE THEY UP TO DATE AND RELIABLE
- DOES THE EU HAVE INPUT INTO THEIR DEVELOPMENT
- WHO VALIDATES THEM?

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A NEW JOINT REPLACEMENT
THE NEXT STEP

- DISCUSSION WITHIN THE COMPANY
- ADVICE AS TO HOW THEY PROCEED
- WHERE CAN THEY GET ADVICE?

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A NEW JOINT REPLACEMENT

THE NEXT STEP
At present

- SUBMISSION TO A NOTIFIED BODY
- ARE ALL NBS THE SAME?
- WHAT ARE THE RULES?

- WHERE DOES “EQUIVALENCE” FIT INTO THE PRESENT REGULATIONS?

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A NEW JOINT REPLACEMENT
THE NEXT STEP

- WHEN WILL THEY HAVE TO UNDERTAKE A CLINICAL EVALUATION

  Do we know?

- WHERE DOES THE NEW EU PANEL FIT IN? WHO TRIGGERS IT

  Do we know?

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A NEW JOINT REPLACEMENT

THE NEXT STEP
POST MARKET SURVEILLANCE

- I HAVE NEVER SEEN A UNVALIDATED PUBLICATION WHICH HAS INCLUDED A PMS STUDY LET ALONE A VALIDATED ONE
- WHY NOT?
- WHAT IS ASKED FOR AT PRESENT?
- WHAT WILL BE ASKED FOR IN THE FUTURE?

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SUFFICIENT CLINICAL DATA

A DEBATE IN ITSELF!

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A NEW JOINT REPLACEMENT

THE NEXT STEP

POST MARKET SURVEILLANCE

WHAT MANY WOULD LIKE TO KNOW!

NOW AND IN THE FUTURE

- HOW RIGOROUS SHOULD IT BE?
- WHAT SIZE OF COHORT
- FOR HOW LONG
- WHAT METRICS SHOULD BE USED
- HOW IS IT VALIDATED

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

- CLINICAL TRIALS
- RCTs ARE EXPENSIVE AND OFTEN NOT COMPLETED
- REGISTRIES ARE USUALLY MANDATORY

- EARLY REGISTRY DATA IS UNRELIABLE
- NOT ALL REGISTRY DATA HAS THE SAME RELIABILITY

- RSA STUDIES HAVE BEEN SHOWN TO ACCURATELY PREDICT EARLY FAILURE

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

- REGISTRIES CAN BE USED AS CONDUITS
- THEY CAN GENERATE QUESTIONS
- THEY CAN STORE ANSWERS

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

THE TOOLS WE HAVE
NOW AND IN THE FUTURE

- RSA STUDIES HAVE BEEN SHOWN TO ACCURATELY PREDICT EARLY FAILURE
- WHAT DOES IT INVOLVE?
- WE HAVE ONE OF THE WORLD'S EXPERTS HERE…. ROB, PLEASE GIVE US A MINUTE!

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

SHOULD RIGOR OF PMS DEPEND ON PERCEIVED RISK

NOW AND IN THE FUTURE

- EVALUATE RISK
- ? STEP BY STEP
- ? QUICK BLAST THEN STOP
- WHO DOES THE MONITORING?

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A NEW JOINT REPLACEMENT
THE NEXT STEP
POST MARKET SURVEILLANCE

SHOULD RIGOR OF PMS DEPEND ON PERCEIVED RISK

NOW AND IN THE FUTURE

- IS BENCHMARKING AN OPTION?
- BENCHMARKING IMPLIES SETTING A STANDARD ACROSS ALL PRODUCTS
- BENCHMARKING USUALLY IMPLIES THE USE OF “NON INFERIORITY” CONCEPT

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A NEW JOINT REPLACEMENT

THE NEXT STEP

POST MARKET SURVEILLANCE

WHERE DO THE RESPOSIBILITIES LIE AND FOR HOW LONG?

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A NEW JOINT REPLACEMENT

THE NEXT STEP

POST MARKET SURVEILLANCE

- WHAT HAPPENS IF AN IMPLANT IS NOT DOING WELL IN ONE COUNTRY?
- WE SHOULD BE ABLE TO INTERROGATE ACROSS ALL EU COUNTRIES

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THE NEXT STEP
POST MARKET SURVEILLANCE

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NORE IMPLANT MONITORING ADVISORY COMMITTEE

IS THIS A GOOD IDEA?

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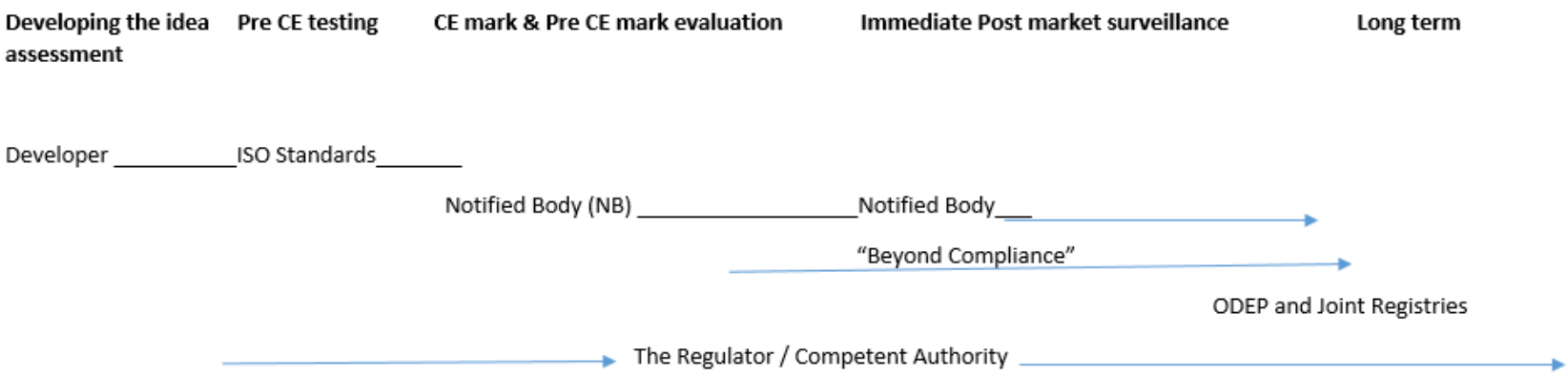
A NEW JOINT REPLACEMENT
HOW SHOULD IT BE INTRODUCED

SURGEONS NEED TO KNOW
MANUFACTURERS NEED TO KNOW

ANSWERS PLEASE!


Developing the idea assessment
Pre CE testing
CE mark & Pre CE mark evaluation
Immediate Post market surveillance
Long term
Developer
ISO Standards
Notified Body (NB)
Notified Body
"Beyond Compliance"
ODEP and Joint Registries
The Regulator / Competent Authority