Implant Registries – impacts for manufacturers, hospitals, governments and patients
35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands
March 27, 2019

Tom Pereboom, chair SVN (Dutch Association for Sterilization); chair of the panel
Andy Crosbie, Devices Division, Medicines & Healthcare products Regulatory Agency MHRA, UK
Dr. Hinne A. Rakhorst, Medisch Spectrum Twente Enschede, Chair Dutch Association of Plastic Surgeons, The Netherlands
Henrik Stilling, Information Technology Architect, Central Denmark Region, Aarhus Hospital, Denmark
Blair Korman, Senior Project Manager Supply Chain Visibility Johnson & Johnson Supply Chain
Implant registries – impact for manufacturers, hospitals, governments and patients

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Mr. Tom Pereboom, chair SVN (Dutch Association for Sterilization)
chair of the panel
March 27th, 2019
Introduction and highlights for this session

- All over the globe regulation drives the unique identification of medical devices.
- The US – FDA regulation with the GUDID drives change concerning identification and registration of medical devices.
- In the EU all stakeholders in healthcare working with medical devices and instruments have to be prepared for the Medical Device Regulation (MDR) and the EUDAMED in 2020.
- Regulation in other countries and regions is expected.
- Preparation is key.
- Implants are a specific type of medical device, and for several reasons patient safety is a major concern.

Several stakeholders have focus on the patient in these processes
Introduction and highlights for this session

“Implant Registries – impacts for manufactures, hospitals, governments and patients”

From their several perspectives the presenters will highlight several issues, such as:

1. Implant registries: why are these important?
2. What is needed to set up registries that are accessible and allow for full traceability?
3. How does GS1 fit in and what can be the added value of GS1?

Ending with Q&A using sli.do.com
Q & A : SLIDO

1. Go to slido.com
2. Enter #GS1HCNoordwijk
3. Select the panel **Implants registries**
4. Go to “Questions”
5. Make sure you enter your full name so that if the questions you’ve raised are not selected, the GS1 team can revert to you
6. Post your questions
Implant Registries – impacts for manufacturers, hospitals, governments and patients

Chair: Tom Pereboom

Andy Crosbie

Dr. Hinne A. Rakhorst

Henrik Stilling

Blair Korman
Regulatory perspective

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Andy Crosbie,
Devices Division, Medicines & Healthcare products Regulatory Agency MHRA, UK

March 27, 2019
Implant Registries - Impacts for manufacturers, hospitals, governments and patients

Regulatory perspective

35th Global GS1 Healthcare Conference - Noordwijk - 26-28 March 2019  
Andy Crosbie – Manager, Post Market Surveillance Strategy - MHRA
Key topics

Why are implant registries important?

What is needed to set up registries that are accessible and allow full traceability?

How does GS1 fit / what can be the added value of GS1?
IMPLANT FILES

Health authorities across the globe have failed to protect millions of patients from poorly tested implants, the first-ever global examination of the medical device industry reveals.
Derek Alderson – RCS President – “there needs to be compulsory registration of every new device and implant that goes into a patient in the UK”.

Surgeons call for compulsory registers of all new medical devices

Rebecca Coombes head of news and views

The BMJ

The government must act urgently to reform the lax regulation system governing medical devices, including a compulsory registry of all new implants, says the Royal College of Surgeons. The call comes after a global investigation by journalists from 36 countries, including The BMJ, BBC Panorama, and the Guardian, into the medical device industry, which unearthed thousands of documents to reveal rising numbers of malfunctions and injuries. The government said that it would work with the UK regulator to see what changes were required. The investigation also provides new evidence of devices being implanted in humans after tests only in pigs or after small scale studies of just tens of patients. The lack of transparency and available data means that the scale of problems remains hidden from doctors and patients. Unlike with drugs, many devices are introduced rapidly onto the market without clinical trial data or centrally held evidence. The president of the Royal College of Surgeons, Derek Alderson, said, “Government needs to address this urgently. There needs to be compulsory registration of every new device and implant that goes into a patient in the UK.
Murray posted this picture on Instagram of his hip following surgery
How long will Andy Murray’s hip replacement last?

Complex question.

Dependent upon a number of independent factors

- Design and durability of the implant
- Surgical technique – skill of the surgeon / instructions for use
- Activity after the procedure
How long does a hip replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up

Jonathan T Evans, Jonathan P Evans, Robert W Walker, Ashley W Blom, Michael R Whitehouse*, Adrian Sayers*

Summary
Background: Total hip replacement is a common and highly effective operation. All hip replacements would eventually fail if in situ long enough and it is important that patients understand when this might happen. We aimed to answer the question: how long does a hip replacement last?

Methods: We did a systematic review and meta-analysis with a search of MEDLINE and Embase from the start of records to Sept 12, 2017. We included articles reporting 15-year survival of primary, conventional total hip replacement constructs in patients with osteoarthritis. We extracted survival and implant data and used all-cause construct survival as the primary outcome. We also reviewed reports of national joint replacement registries, and extracted data for a separate analysis. In the meta-analyses, we weighted each series and calculated a pooled survival estimate for each source of data. This study was registered with PROSPERO (CRD42018085642).

Findings: We identified 140 eligible articles reporting 150 series, and included 44 of these series (13 212 total hip placements). National joint replacement registries from Australia and Finland provided data for 92 series (215 676 total hip replacements). The 25-year pooled survival of hip replacements from case series was 77·6% (95% CI 76·0–79·2) and from joint replacement registries was 57·9% (95% CI 57·1–58·7).

Interpretation: Assuming that estimates from national registries are less likely to be biased, patients and surgeons can expect a hip replacement to last 25 years in around 58% of patients.
Most hip and knee replacements 'last longer than thought'

By Philippa Roxby
Health reporter, BBC News

How long do they last?

Hip replacements: 89% lasted 15 years, 70% lasted 20 years, 58% lasted 25 years

Total knee replacements: 93% lasted 15 years, 90% lasted 20 years, 82% lasted 25 years

Partial knee replacements: 77% lasted 15 years, 72% lasted 20 years, 70% lasted 25 years
MHRA’s use of registry data

Information from the National Joint Registry (NJR) is frequently used by the MHRA as a post market surveillance tool to detect poorly performing orthopaedic devices.

Analysis of data from the NJR was pivotal to MHRA being the first regulator worldwide to publish safety information for clinicians about the risk of soft tissue reactions to metal wear debris in patients implanted with metal-on-metal (MoM) hip replacements (Medical Device Alert MDA/2010/033).
A rare cancer is linked to breast implants and it has killed at least 9 people, FDA warns

Ryan W. Miller  |  USA TODAY
Published 7:08 AM EST Feb 8, 2019

Breast implant-associated anaplastic large cell lymphoma.
Branislav Getty Images/Stockphoto

A rare cancer linked to breast implants has killed at least nine patients since 2010, federal health officials warned this week.

Of the 660 reports of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) received in the past decade, 457 unique cases have now been confirmed, the U.S.
Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin’s lymphoma.

At that time, the FDA knew of so few cases of this disease that it was not possible to determine what factors increased the risk. In a report summarizing the Agency’s findings, we emphasized the need to gather additional information to better characterize ALCL in women with breast implants.

Since 2011, we have strengthened our understanding of this condition and concur with the World Health Organization designation of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces.
BIA-ALCL cases reported to MHRA (UK)

Cumulative total @ September 2018 = 57 cases including 3 deaths

- 45 Confirmed BIA-ALCL
- 4 Confirmed not BIA-ALCL
- 8 Unknown
Examples of questions relating to BIA-ALCL that implant registries can help to answer

What is the incidence of BIA-ALCL?

How long after device implantation does BIA-ALCL occur?

Are textured implants more likely to be associated with BIA-ALCL than smooth implants?

Are devices made by one particular manufacturer more likely to be associated with ALCL cases?
26 November 2018

**A statement on breast implant safety**

Breast implants are amongst the most used and most highly studied implantable medical devices in the world. Important lessons were learned from historical incidents which have resulted in improvements in the international regulatory system and the widespread introduction of national breast implant registries.

The establishment of effective national breast device registries combined with international collaboration has the ability to significantly improve health outcomes for patients with implantable breast devices globally.
Value of registries

Registries have the demonstrated ability to be a key part of healthcare quality assurance systems by providing information about both device safety/performance and variability of clinical practice that is:

- comparative
- transparent; and
- tailored

to the needs of patients, medical device regulators, other healthcare regulators and healthcare professionals/institutions.
Registry information can be of significant value to:

- **patients** - safety of the devices / clinical practice of the healthcare professionals and institutions
- **healthcare regulators (such as MHRA)** - to inform regulatory decision-making - device safety and performance
- **manufacturers** - monitoring of the safety and performance of their devices throughout their lifecycle
- **healthcare professionals and professional institutions**
  - clinicians about their clinical performance in comparison with their peers
  - professional bodies - in support of clinical audit
  - decision making about choice of devices
Integration of key elements of post-market surveillance

Adverse incident reporting

Post-Market Clinical Follow-up (PMCF)

Post Market Surveillance

Implant Registries

GS1 GTINs are one of the most widely used types of Unique Device Identifiers (UDI) for regulatory applications.
Key requirements for effective registries – MHRA’s perspective

In order to be effective, it is vital that registries, should have:

- clearly defined **aims and objectives** which are accepted by key stakeholders
- sustainable **long-term funding**
- **governance structures** which ensure data confidentiality, transparency and appropriate reporting / feedback to key stakeholders
Eight qualifiers that define the impact, value and sustainability of a registry – regulatory perspective

- Includes sufficient device information (unique device identification)
- Is part of a health care delivery quality improvement system or is evolving into one
- Has established mechanisms to bring about beneficial change in health care delivery
- Is embedded in the healthcare delivery system. Data collected as part of care delivery - collection integrated with work flow of clinical teams
- Provides actionable information to decision makers in a relevant and timely manner
- Should be transparent (governance structure, data access and analytic processes)
- Information can be linked with other data sources
- Can serve as infrastructure for seamless integration of evidence throughout the device life cycle
Integration of data collection

Registries should be embedded in the health care delivery system with data collection being integrated with work flow of clinical teams using (for example) scanning technologies. The feasibility of this approach has been successfully demonstrated in England by the Scan4Safety initiative.
Using scanning approach will help to improve patient safety – implant tracking and surveillance

+ convergence with registries / real world data collection

- Implant / patient track-&-trace
- Post-market safety monitoring

More accurate and convenient registry and real world data collection
GS1 core enablers can support registry data collection

Deliverables – Initial Core Enablers

- **Location Identification**
  - Implementing GLNs, a global standard for location identification
  - Unique Location Identification

- **Patient Identification**
  - Wristbands GSRN compliant can be scanned by patient systems
  - Unique Patient Identification

- **Catalogue Management**
  - All relevant processes use the GTIN as the primary product identifier
  - Unique Device Identification
MHRA supports the development of registries

MHRA supports the development of a comprehensive system of medical device registries (with particular focus on implantable devices) in support of patient safety.

This would be in line with new European regulations for medical devices* (coming into effect in May 2020) which:

➢ encourage the establishment of registries (Article 108); and
➢ introduce the use of Unique Device Identifiers and their capture within healthcare records (Article 27).

*European Medical Device Regulation (EU) 2017/745
Thank you.

andy.crosbie@mhra.gov.uk
35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Dr. Hinne A. Rakhorst, Medisch Spectrum Twente Enschede,
Chair Dutch Association of Plastic Surgeons, The Netherlands

March 27, 2019
Implant registries

A work floor perspective

Hinne Rakhorst
Babette Becherer, Marc Mureau, Juliette Hommes, Xavier Keuter, Annelotte van Bommel, Danny Young Afat, Marije Hoornweg
All plastic surgeons in the Netherlands
Disclosures

None other than voluntary professional board work
No connections to industry
Thank you
Who knows someone with breast implants?
Estimate
1:30 adult Dutch women

Approximately the same as hip arthroplasties
70% vs 30%

Esthetic vs Reconstructive
Many types, few variables

Texture; Smooth vs macrotextured vs microtexture vs nanotexture
Shape; Round vs Anatomical
Fill; Saline fill vs silicone vs methylcellulose vs air
Coating; Silicone vs polyurethane coating
Duration; Temporary (tissue expander) vs Permanent

Large international variation in preference
Breast implants are safe implants, class III
Breast implants have adverse events
Breast implants often need revision surgery

AESTHETIC

- Primair (n=12,513)
- Revisie (n=768)
  Gemiddelde leeftijd:

RECONSTRUCTIVE

- Primair (n=4,934)
- Revisie (n=824)
  Gemiddelde leeftijd:

*Replacement of TE for Implant is excluded
what happens in (social) media

FDA Kept Hundreds of Thousands of Breast Implant Incidents Hidden From Public

The U.S. Food and Drug Administration held a public hearing into breast implant safety.
Breast implants have serious adverse events
uproar in society

so what to tell ;
The exception?
The rule?
Auditions sur les implants mammaires texturés en chirurgie esthétique et reconstrctrice (Partie 2)
Let's stick to the evidence in respect to 3% of all women.
What is the evidence?
What is the risk?
Risk;
\[
\frac{\text{Numerator}}{\text{Denominator}}
\]
Number of cases

Total number of women that have implants
Challenge

≈ Rough estimate number of cases

≈ Rough estimate number of women that have implants
Challenge

≈ Rough estimate number of cases

≈ Rough estimate number of women with types of implants
Solution come when we know about;
Numbers
Types
So register these data
Conclusion of all scientists and governments

• Need more data
• More transparency
• Need registries
Basic implant registry; L.I.R. (NL) =

Clinical registries; =

EUDAMED
EUROPEAN DATABANK ON MEDICAL DEVICES
What do you think I do all day?
My surgical working day

Registration time
Surgery

• 1-8 patients
• Surgery is great
• ‘turn over time’ is 5 minutes
  • Write surgical report
  • Write discharge letter
  • Pills
  • Call family
  • focus on next case, read notes
  • Say hi to next patient
  • Mark up next patient

• Have coffee
• EXTRA TIME
Need to register data
Need to register data
Big data
Need to register data
Big data

NO TIME!
Dutch Breast Implant Registry
DBIR
Clinical registry
Start 2015

National
All patients
All procedures
<table>
<thead>
<tr>
<th><strong>Patient;</strong></th>
<th><strong>Surgery</strong></th>
<th><strong>Implant</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>name</td>
<td>L / R / L + R</td>
<td>Shape</td>
</tr>
<tr>
<td>Age</td>
<td>Cosmetic/reconstructive</td>
<td>Texture</td>
</tr>
<tr>
<td>History?</td>
<td>New or exchange</td>
<td>Fill</td>
</tr>
<tr>
<td>other diseases</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Patient characteristics

<table>
<thead>
<tr>
<th>Nature of indicator</th>
<th>Possible values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique patient number, clinic*</td>
<td></td>
</tr>
<tr>
<td>ASA classification before operation*</td>
<td>A normal healthy patient, A patient with a mild systemic disease, A patient with a severe systemic disease that limits activity but is not incapacitating, A patient with an incapacitating systemic disease that is a constant threat to life, A moribund patient not expected to survive 24 hours with or without operation, ASA unknown</td>
</tr>
<tr>
<td>Nicotine abuse*</td>
<td>Yes, No, Not known</td>
</tr>
<tr>
<td>Height in centimeters*</td>
<td></td>
</tr>
<tr>
<td>Weight in kilograms*</td>
<td></td>
</tr>
</tbody>
</table>

### Side of operation*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td></td>
</tr>
</tbody>
</table>

### Indication of surgery*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cosmetic augmentation</td>
<td></td>
</tr>
<tr>
<td>Reconstruction post cancer</td>
<td></td>
</tr>
<tr>
<td>Reconstruction benign</td>
<td></td>
</tr>
<tr>
<td>Congenital deformity</td>
<td></td>
</tr>
<tr>
<td>Reconstruction post prophylactic mastectomy</td>
<td></td>
</tr>
</tbody>
</table>

In case of revision, register indication and timing (if applicable) of primary surgery.

### Weight/Volume of implant (cc or gr)*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Texture*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Textured</td>
<td></td>
</tr>
<tr>
<td>Smooth</td>
<td></td>
</tr>
</tbody>
</table>

### Coating*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone</td>
<td></td>
</tr>
<tr>
<td>Polyurethane</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

### Fill*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Silicone</td>
<td></td>
</tr>
<tr>
<td>Saline</td>
<td></td>
</tr>
<tr>
<td>Hydrogel</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

### Shape*

<table>
<thead>
<tr>
<th>Choice</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round</td>
<td></td>
</tr>
<tr>
<td>Shaped / Anatomical</td>
<td></td>
</tr>
</tbody>
</table>
Results
DUTCH BREAST IMPLANT REGISTRY (DBIR)
ANNUAL REPORT 2015 – 2017

DBIR
DUTCH BREAST IMPLANT REGISTRY
40,000 implants


Total number of

- Patients ± 18,000
- Operations ± 20,000
- Implants ± 38,000
Vendor distribution
International Collaboration of Breast Registry Activities
Breast Devices

Predicted Annual Number of Breast Devices

Total: 1,032,900
ICOBRA MINIMUM DATA SET; implant

- UDI; serial number/Lot
- Producer
- Texture
- Fill
- Shape
- Volume of implant
International professionals all want the same data
ICOBRA set of minimum datapoints
We have an international professional standard
140,000 implants up to 2017
Lessons learned;

• Reduce typo’s
• Reduce interpretation errors
• Reduce administration time
• Enhance re-use of already registered data
• Use IT
• Enhance reliability in tracing and output
What would help?

• A single identifier for an implant
What helps?

• UDI Unique device Identifier
What did we do to make use of UDI?
From the start;

• Ask industry for support
• Ask government for guidance

• Made it functional
DBIR
DUTCH BREAST IMPLANT REGISTRY

General Information:
- Registration of a patient is finished when all errors (1) have disappeared.
- Please visit the DICA website for instruction videos (section DBIR - Documentation).
Barcode functionality;

• Less typos
• Quicker entry
• More reliable output;
  • Manufacturer
  • Surgeons
  • Patients
  • society
Future
More automation
Unique Device Identifier
Key to

Fixed number of globally agreed device datapoints
stakeholders

• Surgeons
• Patients
• Hospitals
• Industry
• governments
Workfloor wants registries

Workfloor wants efficient data entry

Hinne Rakhorst
Babette Becherer, Marc Mureau, Juliette Hommes, Xavier Keuter, Annelotte van Bommel, Danny Young Afat, Marije Hoornweg
All plastic surgeons in the Netherlands
Implant Registries
Impact and solutions for hospitals

Henrik Stilling, IT-Architect, Aarhus University Hospital, Central Denmark Region
GS1 Healthcare Conference, Netherlands, March 2019
Disclaimer

Any barcodes or pictures of devices that might relate to real-world products in this presentation is unintentional.

Any critique or problems discussed in this presentation caused by devices or in the process of identifying devices is in no way intended to be relatable to named manufacturers.

All illustrations are intended as unidentifiable examples. Pictures of personnel and operating rooms are staged for educational purposes and are the copyright of Central Denmark Region and may be distributed by GS1 and affiliates as a part of this presentation.
Henrik Stilling

Who am I?

- Central Denmark Region
- Lead architect for item identification and tracking
- Engineer by trade
  - Process management
  - Technology adaption
- Worked within health care industry since 2008
- Part of Danish national initiative on identification and traceability in healthcare
Overview

- Mandatory for all use of surgical implants from 1st of July 2018 and onwards
- Register implantable devices to a given patient
  - CPR
  - GTIN
  - Device attributes
    - Batch/Lot/Serial
    - Manufacturing date/Expiry date
    - ...
Traceability, transparency and fulfilment

Clinical process

- Correct implant for the right patient
- Agility
- Flexibility
- Decision support
- Use before expiry date

Supply chain

- Just in time
- Minimize storage
- Use before expiry date
- Optimal selection of implants
Setting the scene
Setting the scene

OPERATING ROOM

Patient
Goods supply
Instruments
Unused goods
Disposables
Patient
Instruments
Realtime registration
Multi-platform hybrid registration
Multi-platform hybrid registration

...no two surgical specialties are the same!
## Completeness, quality and optimization

### Datasource
- GS1 Application Identifiers
- GTIN
- Expiry
- Batch
- Serial

### Possibilities
- Making the adequate choice
- Making the best choice
- Use before expiry date
- Use in order of expiry
- Know what drives your bottom line
## Getting the data

<table>
<thead>
<tr>
<th>Prefered</th>
<th>Usable</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="QR Code" /></td>
<td><img src="image" alt="Barcode" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exotic</th>
<th><img src="image" alt="RFID Tag" /></th>
</tr>
</thead>
</table>
Getting the data

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Usable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single scan</td>
<td>Complex scan</td>
</tr>
<tr>
<td>(Qr code)</td>
<td>(Barcode)</td>
</tr>
<tr>
<td>(01)05712685999993</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exotic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low availability</td>
</tr>
<tr>
<td>Expensive scan</td>
</tr>
</tbody>
</table>
Registering correctly - requirements

- Define best practice
- "Closed loop scanning"
- Quality barcodes
Registering correctly - results

- 1 in 20 manual registrations contains errors
- Scanning is simple...
- Scanning the wrong data is even easier
- Real-time scanning is a driver and safety asset when used correctly
- Easy to implement but requires a high level of understanding to use
Next steps

- Further development
- Training
- Implant registries are not a goal in its own right
  - Clinical quality and safety
  - Overview and decision support
  - Have data available before use
  - Supply chain
- Why can’t we scan all available information?
- Now we’re registering – what about recalls?
Using UDI to support Product Registry

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

Blair Korman,
Senior Project Manager Supply Chain Visibility Johnson & Johnson Supply Chain

March 27th, 2019
Using UDI to support Product Registry

Blair Korman
GS1 Global Healthcare Conference
Noordwijk, Netherlands
27.March.2019
Presentation Overview

Introductions

UDI Landscape and Timelines

Aspects of UDI

Leveraging the UDI Data
We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality. We must constantly strive to provide value, reduce our costs and maintain reasonable prices. Customers’ orders must be serviced promptly and accurately. Our business partners must have an opportunity to make a fair profit.

We are responsible to our employees who work with us throughout the world. We must provide an inclusive working environment where each person must be considered as an individual. We must respect their diversity and dignity, and recognise their merit. They must have a sense of security, fulfilment and purpose in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must support the health and well-being of our employees, and help them fulfil both their family and other personal responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide highly capable leaders, and their actions must be just and ethical.

We are responsible to the communities in which we live and work, and to the world community as well. We must help people to be healthier by supporting better access and care in more places around the world. We must be good citizens – by supporting good works and charities, improving health and education, and bearing our fair share of taxes. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programmes developed, investments made for the future and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realise a fair return.
Johnson & Johnson Portfolio

Consumer

Baby Care • Body Care • Facial Skin Care • Sun Care • Feminine Personal Care • Allergy Care • Compromised Skin Care • Cough and Cold Care • Digestive Health • Oral Care • Pain Care

Medical Devices

Wound Closure & Surgical Devices • Minimally Invasive Surgery • Joint Replacement • Sterilization • Eye Health • Diabetes Care

Pharmaceuticals

Oncology • Infectious Diseases & Vaccines • Immunology • Cardiovascular & Metabolism • Neuroscience & Pain • Pulmonary Hypertension
# UDI Global Data Access

<table>
<thead>
<tr>
<th>Country</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU MDR</td>
<td>Public access database is planned via EUDAMED system Data submission to be uploaded by May 2020</td>
</tr>
<tr>
<td>UK NHS</td>
<td>Data access via GDSN must register with certified data pool Data for all device classes available for J&amp;J products</td>
</tr>
<tr>
<td>Turkey</td>
<td>Data available in country via UTS product registry since July 2017 An aspect of UTS includes track &amp; trace</td>
</tr>
</tbody>
</table>

UDI is expanding around the globe..........
### Global UDI Activity

** Regulations expected to impact 2019 activities

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>UDI Draft issued, likely</td>
<td>includes data, labels, direct mark</td>
</tr>
<tr>
<td>Korea</td>
<td>UDI Draft issued,</td>
<td>with limited details but includes UDI data, labels, direct mark, track &amp; trace</td>
</tr>
<tr>
<td>Taiwan</td>
<td>No draft issued,</td>
<td>provided sample GUDID data</td>
</tr>
<tr>
<td>Brazil</td>
<td>UDI regulation published,</td>
<td>impacts hip and knee implants (similar to Argentina)</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>UDI Draft issued, based on</td>
<td>IMDRF expected to include data (SAUDID), labels, and direct mark. Track &amp; trace expected.</td>
</tr>
</tbody>
</table>

*UDI Draft issued, likely includes data, labels, direct mark*

*UDI Draft issued, with limited details but includes UDI data, labels, direct mark, track & trace*

*No draft issued, but provided sample GUDID data*

*UDI regulation published, impacts hip and knee implants (similar to Argentina)*

*UDI Draft issued, based on IMDRF expected to include data (SAUDID), labels, and direct mark. Track & trace expected.*
UDI Overview
Common components included in UDI regulations

Data Repositories
Label Requirements
Direct Marking
What to Leverage in the UDI Data

- Unique Device Identifier ➔ GTIN, HIBCC, other ➔ The DI
- Other searchable criteria include catalog or reference number
- Monthly GUDID full downloads are available for all devices
- UDI Nomenclature provides searchability to like devices
- Source of truth for data and identifying new products
How to Leverage the UDI Data

Scan the UDI DI

Access UDI database and include in registry

Improve data methods
Thank you
Q & A : SLIDO

1. Go to slido.com
2. Enter #GS1HCNoordwijk
3. Select the panel **Implants registries**
4. Go to “Questions”
5. Make sure you enter your full name so that if the questions you’ve raised are not selected, the GS1 team can revert to you
6. Post your questions
Implant Registries – impact for manufacturers, hospitals, governments and patients

Questions and wrap-up

35th Global GS1 Healthcare Conference, Noordwijk, the Netherlands

March 27th, 2019
Thank you very much for your attention

March 27th, 2019