Medical Device Databases.
Global practices

Gleb Donin
Medical device life span phases

- Development
- Manufacture
- Packaging & labeling
- Sale
- Advertising
- Use
- Disposal
Information groups

Essential
Trial
Registration
Market
Performance
States medical device databases

Registration process

- Trials
- Classification
- Approval

Development & labeling
Placing on the market
Advertising
States medical device databases

Registration

Approved medical devices database

Free access

• USA
• Singapore
• Australia

Limited access

• EU
• Russia
Medical Device Nomenclature

GMDN

- Global Medical Device Nomenclature
- Used by many countries in registration process for medical device classification
- No free access

UMDNS

- Universal Medical Device Nomenclature System
- Used in HIS, post market surveillance, for inventory control, etc.
- Free basic access
Eudamed Intro

European Databank on Medical Devices

• Secure web-based portal for rapid information exchange between national authorities
• Decision obliges Member States to use EUDAMED from 1st May 2011
• Contains:
  - Registrations
  - Certificates
  - Vigilance
  - Clinical investigations
Eudamed
Czech Republic

Ministry of health

- Medical device manufacture/authorized rep.

SUKL

- Vigilance
- Clinical investigations

UZIS

Certificates issued by Notified Bodies
## Eudamed Information required

### Registration Details
- Actor (manufacturer /authorized rep.) details:
  - Name, address, contacts etc...
- Device details:
  - Name, model
  - GMDN code

### Certificate Details
- Certificate number
- Certificate type
- Date of issue & expiration
- Manufacturer/authorised rep
- Notified Body
- General Scope description
- Status
# Eudamed Information required

## Incidents (NCAR) Details
- Competent Authority reference
- Manufacturer/authorised rep.
- Device, plus where applicable lot number, serial number, software version
- Background Information (Description)
- Conclusion
- Recommendation
- Action and action description

## Clinical Investigation details
- Manufacturer/authorised rep.
- Device
- Title of investigation
- Protocol number
- Primary objective
- Competent Authority
- Decisions taken by Competent Authority
- Early termination on safety grounds pursuant
<table>
<thead>
<tr>
<th>Essential</th>
<th>Trials</th>
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Italy Medical Device Databank

DataBank and Repertory of medical devices
- Manufacturer’s Data
- Medical device’s data
- Medical device’s documentation
- CE Certification’s data

- At present, about 290,000 medical devices are recorded in the “Data Bank and Repertory of medical devices”
- Used National Classification of Medical Devices and GMDN
- Access is allowed only to Italian healthcare organizations
Italy
Consumption Monitoring

The Data Bank for monitoring consumptions of medical devices directly acquired by Italian NHS

- Purchasing contracts
- Distribution of purchased medical device in healthcare units

Uploading a XML file

Healthcare organizations

National Healthcare Informational System
Italy Consumption Monitoring

**Contract**
- **Header**
  - Region code
  - Healthcare organization
- **Devices**
  - MD code
  - Quantity
  - MD price
  - VAT
- **Contracts**
  - Contract ID
  - Contract date
  - Duration

**Distribution**
- **Header**
  - Region code
  - Healthcare facility
  - Report period
- **Devices**
  - MD code
  - Healthcare unit
  - Quantity
  - MD price inc. VAT
USA

Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services.

FDA database with free access:
- Premarket Approvals (PMA)
- Premarket Notifications (510(k)s)
- MAUDE (Manufacturer and User Facility Device Experience)
- Medical device recalls
- Total Product Life Cycle

- Registration & Listing database

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
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Russia Medical Devices Regulation

- **Minzdrav**
  - Ministry of Health and Social Development

- **Roszdravnadzor**
  - Federal Service On Surveillance in Healthcare and Social Development

- **VNIIIMT**
  - All-Russian Scientific, Research and Testing Institute for Medical Devices
VNIIIMT’s Informational System for Monitoring of Medical Devices (AISMMI)

Control medical device on all phases of it’s life cycle:
• Central reference database on medical devices
• Control purchasing medical device by healthcare facilities
• Control medical device performance in healthcare facilities
Russia
AISMMI

AISMMI’s Databases

Medical Device Reference Database
VNIIIMT

Medical Device Performance Database
Healthcare Facilities
Russia
AISMMI

Reference Database

Inventory standards

Registration info

Normative documents
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- **Trials:** Clinical, Technical
- **Market:** Supplier, Price, Price structure, Purchase inf., Contract options
- **Performance:** Adverse events, Operating time, Idle time & reason, Life cost, Medical procedures, Maintenance, Efficiency, Inventory
VNIIIMT
AISMMI

• Reference database is used as a base for monitoring of medical device in healthcare facilities

• Today AISMMI is used for control performance of medical devices purchased by federal budget

• More than 4000 Healthcare Facilities
• More than 80000 medical devices
<table>
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<th>Inventory monitoring</th>
<th>Purchasing contracts</th>
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<td>Medical device purchasing prices</td>
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<td>Healthcare facility’s medical devices</td>
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<td>Accordance with inventory standards</td>
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<td>Inventory monitoring</td>
<td>Using of medical devices</td>
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<td>Idle period &amp; idle reason</td>
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<td>Consumable items quantity and cost</td>
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AISMMI

Controlling parameters

• **Operating time** – operating life assessment and replacement planning

• **Idle time & idle reasons** – reliability of medical devices and technical efficiency

• Gathering quantity and prices of consumable items - **life cost**

• **Maintenance contracts and prices** – life cost, reliability, technical efficiency

• **Inventory** - accordance with inventory standards and purchasing planning
ECRI Institute

- Nonprofit healthcare information organization founded in 1968
- Collaborating Center, World Health Organization
- Produce 35 databases and publications
- Operate under very strict conflict of interest rules
- More than 380 full time staff in 4 offices (Pennsylvania, Kuala Lumpur, London, Dubai)
- Largest information provider worldwide for healthcare technology—its assessment, planning, selection, procurement, management, and risk and quality assessment

www.ecri.org
www.ecri.org.uk
ECRI Institute Information Sources

- CEMS
  - Healthcare Facilities

- Standards

- Experts

- Other databases

- Manufacture’s info

- Testing laboratories
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ECRI Institute
Products & Services

- Universal Medical Device Nomenclature System™
- Healthcare Product Comparison System
- Sourcebase Online and Health Devices Sourcebook
- Health Technology Assessment Information Service
- SELECTplus™ Healthcare Technology Advisory
- PriceGuide™ Advisory Membership Service
- And many others
UMDNS - Universal Medical Device Nomenclature System:

- The 2011 UMDNS contains more than 26,000 medical device terms
- Formal, hierarchical system for organizing device-related information
- Not simply a list of products: a database
- Dynamic: maintained and updated continuously to reflect advances in medical
- Constant monitoring to maintain and improve quality
- Worldwide user feedback a critical input for UMDNS
Sourcebase is an online database of manufacturers and distributors of medical devices.

- Cross-reference companies and devices for easy searching.
- Trade names, key contacts, and company certifications.
- View standardized nomenclature
Health Product Comparison System

- Online database of 450 types of devices
- Side-by-side model specifications
- Offers unique model specific comparisons
ECRI Institute
HPCS

Report contains:
• Purpose and principles of operation
• Reported problems
• Purchase considerations
• Present value/Life cycle cost analysis
• Bibliography
• Standards and Guidelines
• Citations from other ECRI Institute sources
• Supplier Information
• Product comparison chart
ECRI Institute
HPCS

- Full-text searchable by device, manufacturer name, medical procedure, or model name
- Links to product literature and cut sheets
- Easily print and export reports, figures
- Dynamic supplier lists from Sourcebase
### ECRI Institute HPCS

- **Key parameters of medical device**
- **ECRI Institute Recommended Specifications**

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<tr>
<th>Model</th>
<th>ECRI Institute's Recommended Specifications</th>
<th>ADAN</th>
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<tbody>
<tr>
<td></td>
<td>Radiographic Chest Units, Digital</td>
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<td></td>
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<tr>
<td></td>
<td>Radiographic Chest Units, Film</td>
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<table>
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<tr>
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<tr>
<td>CE MARK (MDD)</td>
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<tr>
<td>TYPE</td>
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<td>Film (manual)</td>
<td>II B</td>
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<tr>
<td>MAXIMUM IMAGE SIZE, cm (in)</td>
<td>43 x 43 (17 x 17)</td>
<td>All standard film sizes</td>
<td>41 x 41 (16 x 16)</td>
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<tr>
<td>Cycle time, sec</td>
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<td>Images/hr</td>
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<td>PIXEL SIZE, μm</td>
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<td>50-180 (19.7-70.9)</td>
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