Innovation for Safety: Achievements and Challenges

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DITTA - the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association

- DITTA is a global organization representing industry associations of manufacturers around the world

- DITTA, a non-profit trade association, has represented this industry for more than 12 years
Member companies manufacture:

- medical x-ray equipment
- computed tomography (CT) scanners
- ultrasound
- radiation therapy equipment
- nuclear imaging
- magnetic resonance imaging (MRI)
- medical software
- imaging information systems
- health IT
- radiopharmaceuticals
Examples of Innovation

**Diagnostics**
- Faster, accurate imaging
- Molecular imaging
- Miniaturisation/portability
- Point of Care diagnostics
- Therapy selection/monitor

**Biotech & Genomics**
- Targeted therapy
- Proteomics/DNA
- Biomarkers
- Rapid screening tools
- Vaccine development

**IT & bioengineering**
- eHealth/Telemedicine
- Mobile solutions
- BioSensors
- Computer Aided Diagnostics
- Patient monitoring
Example: Imaging in Breast Cancer

Diagnosis of Recurrence
Detection of Residual Disease
Therapy Evaluation
Therapy Selection
Staging
Diagnosis
Screening
Predisposition

Breast Cancer Disease Management Track

Genomics
BRCA 1,2
Risk Profiling

Ultrasound
MR

PACS
Electronic Health Record
Medication Management

Microarray
Proteomics
CT MR
PET/CT Nuclear Med

PET/CT Functional Marker
CTMRI Radiation Treatment

Mammography In-vitro test
F-Angiogenesis PET

PET/CT New markers

Optical Functional Marker

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Exist Today
Emerging Research and Technologies
Product Lifecycle: Continuous Improvement

Stakeholders are key in providing input on safety: patients, HCPs, regulators, CIOs, etc.

State-of-art international standards are the foundation to the full product lifecycle

Milestones for Patient Safety focus
Challenges

- **Lack of:**
  - Harmonized regulatory framework
  - Internationally recognized standards
  - Common data set for product registration
  - Common process for postmarket requirements

- **Impact on time to market (in all geographies):**
  - Access to clinical solutions
  - Quality of care

- **Increase of:**
  - Integrated care
  - HomeHealth
  - Aging populations
  - Non-communicable chronic disease
  - Patient empowerment
  - Demands for healthcare
An Example Solution – CT Dose

Joint Task Forces
- Goal – CT dose optimization
- Stakeholders – patients, physicists, healthcare professionals, equipment designers and manufacturers, regulators, hospital managers, etc.

Commitments
- Analyze problem, identify potential root causes, develop solutions
- Implement dose optimization measures, e.g., in standards
- Establish dose management, recording and reporting
- Provide extensive multimedia training curricula

Adoption
- As technology progresses, CT manufacturers provide clinical image quality at lower doses

Innovation
- Continued investment in dose reduction without compromising diagnostic accuracy
- Expand model to other modalities
Future Trends

• Demand for rapid development of telehealth, mobile health, cloud computing, remote care, etc.
• Protecting patient data and cybersecurity
• Software as a medical device

• Integrated technologies (product and services) to cover the continuum of care

• Local manufacturing (regulatory pressure, cost of labor, proximity to resources and raw materials)
• Increasingly complex, global supply chain
• Ancillary regulation compliance (recycling, transportation of used parts/waste)

• Building clinical and socio-economic evidence for innovative technologies
Processes and Communication Supporting Safety

**Training**
- Industry, healthcare professionals (HCPs) and patients
- Technology and intended use
- In person, on site, and on-line

**Technical Support**
- Ongoing support for HCPs/patients
- Preventive maintenance programs
- Remote diagnostics and upgrades

**Improvements**
- Product upgrades
- Preventive and corrective actions

**Safety Alerts**
- In person, letters, on-line alerts
- Regulator consultation
- Adverse event reporting, recalls
Recommendations to Stakeholders

1. Further **harmonize** the global regulatory framework

2. Continue promoting **active partnering** with all stakeholders in the implementation of innovative and safe technologies

3. Increase **awareness** through shared responsibility in providing effective **education**
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The Way Forward

THANK YOU!