



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

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



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

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



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Examples of Innovation

Diagnostics

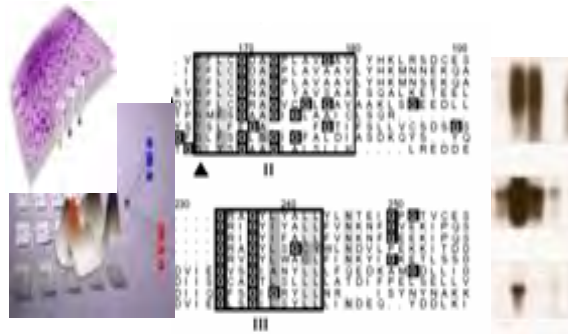
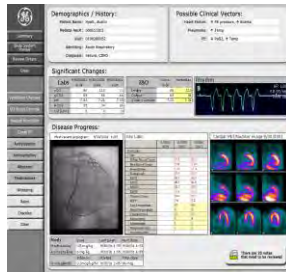
- Faster, accurate imaging
- Molecular imaging
- Miniaturisation/portability
- Point of Care diagnostics
- Therapy selection/monitor

Biotech & Genomics

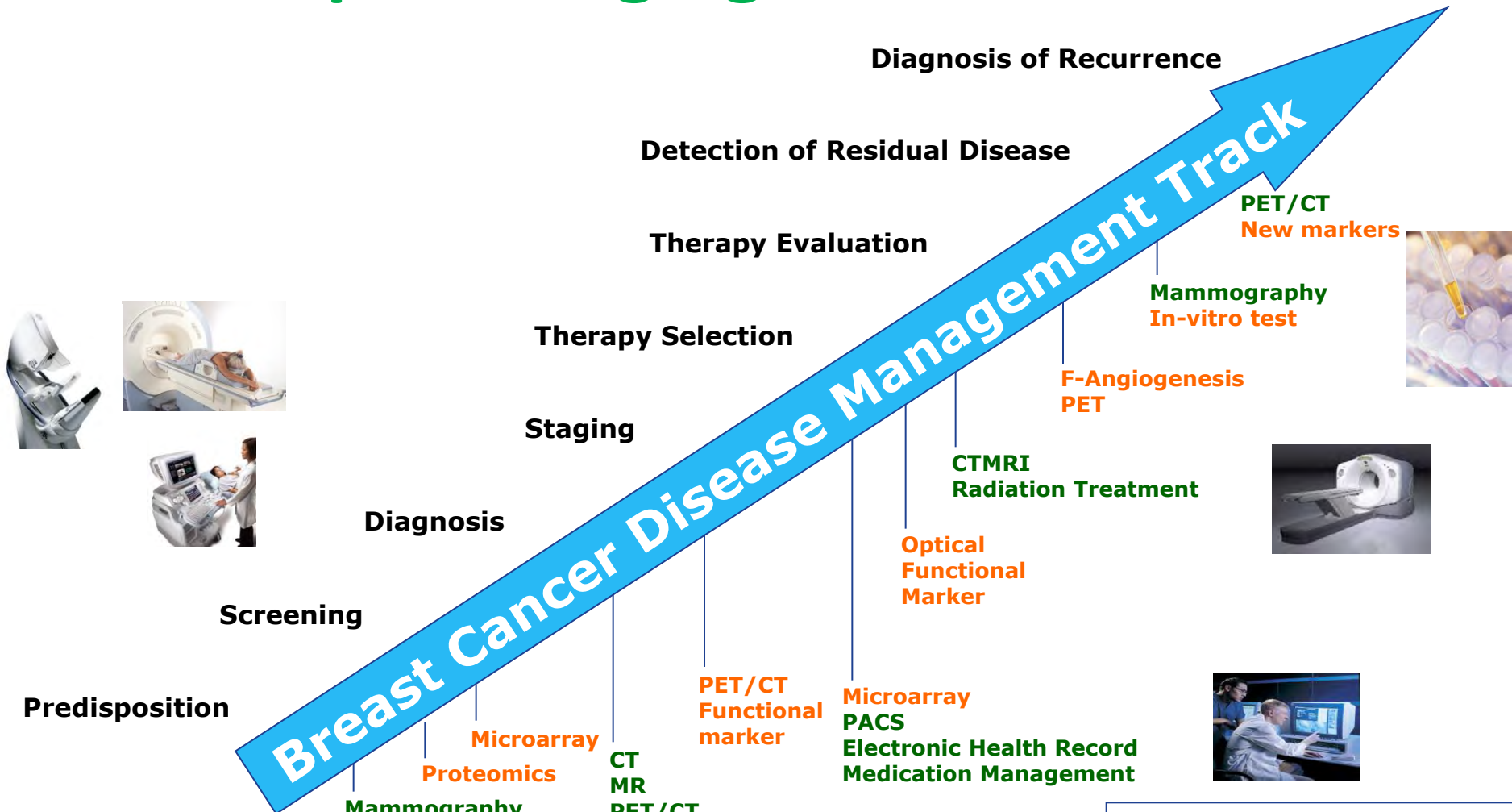
- Targeted therapy
- Proteomics/DNA
- Biomarkers
- Rapid screening tools
- Vaccine development

IT & bioengineering

- eHealth/Telemedicine
- Mobile solutions
- BioSensors
- Computer Aided Diagnostics
- Patient monitoring



Example: Imaging in Breast Cancer



Exist Today

Emerging Research and Technologies

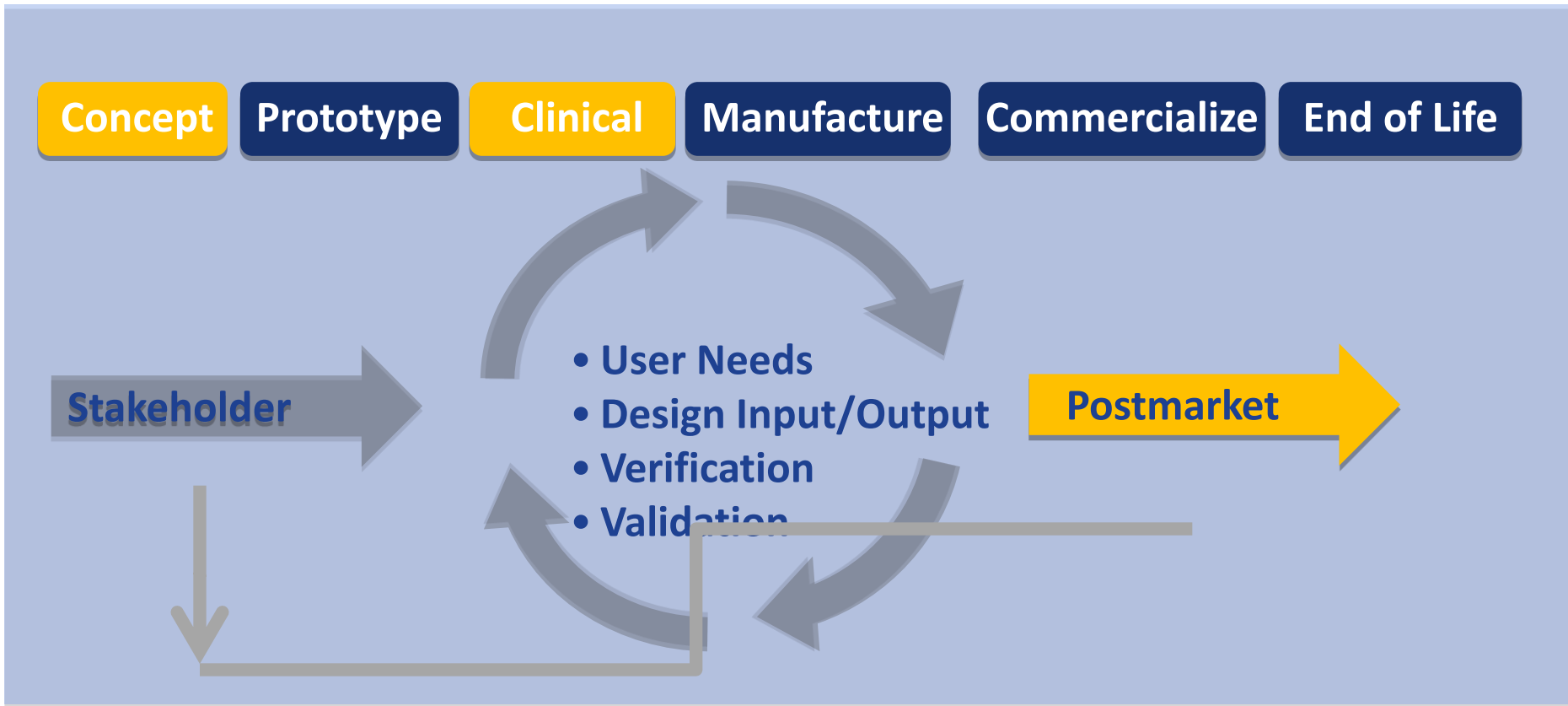


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Product Lifecycle: Continuous Improvement

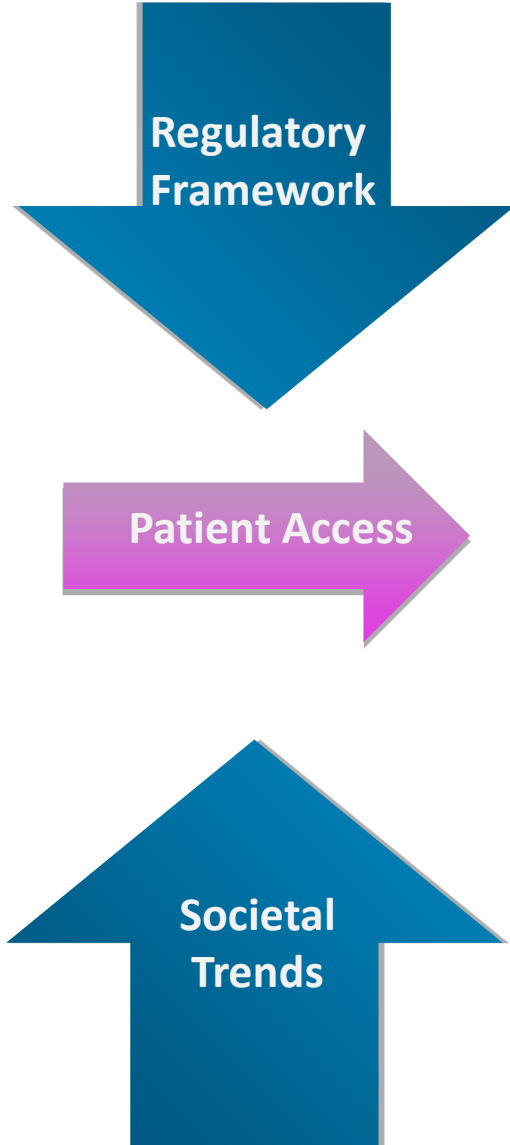
Stakeholders are key in providing input on safety:
patients, HCPs, regulators, CIOs, etc.



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

Health IT

- 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

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

Global Manufacturing

- 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)

Health Tech. Assessment

- 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

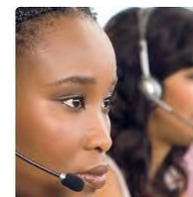


Technical Support

- 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 !



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