INTRODUCTION TO DITTA

22nd AHWP Annual Meeting

4-8 Dec 2017, Delhi, India

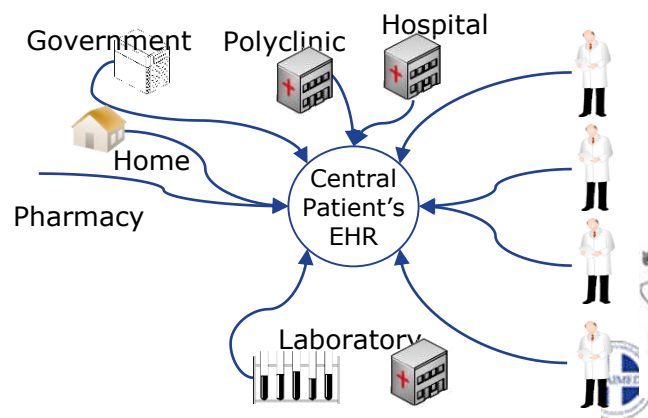## Peter Linders

DITTA Board of Director Member

DITTA is a non-profit trade association, created in 2000 and incorporated in 2012 represents more than 600 companies around the globe

DITTA covers the following industry sectors:
1. Diagnostic imaging,
2. Radiation therapy,
3. Healthcare IT,
4. Electromedical
5. and Radiopharmaceuticals

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle

DITTA GLOBAL PRESENCE

DITTA GOVERNANCE

Board of Directors

DITTA Chair:
Patrick Hope, MITA Executive Director
DITTA Vice-Chairs:
Nicole Denjoy, COCIR Secretary General
Satoshi Kimura, JIRA Executive Director

Members:
•Founding Organisations
•Executive Mgmt of each organisation
•Chairs of their International Groups

Steering Committee

Chair: DITTA Chair
Members:
• Heads of each organisation
• Leadership of their International Groups
• Leadership of DITTA WGs

TCONs: one per month

Working Groups

One Chair, Two Vice-Chair per Working Group
Members:
•   Mixture of trade associations and company experts
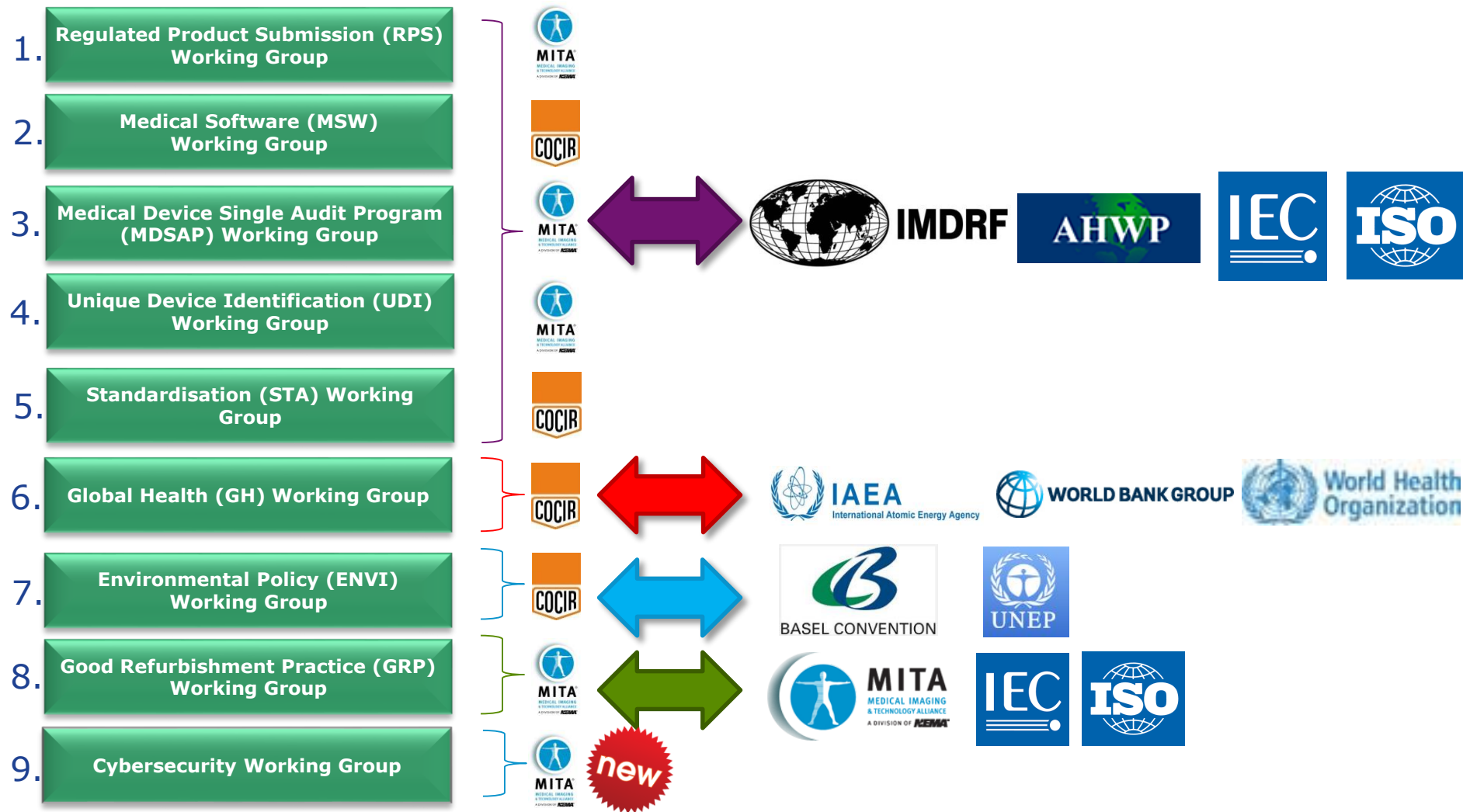•   Coordination: MITA or COCIR

TCONs: as needed

DITTA: 9 WORKING GROUPS

DITTA PAST INVOLVEMENT IN AHWP

DITTA is happy to participate in AHWP since 2011

DITTA covered the following topics in past AHWP meetings:

- Refurbishment of Medical Imaging Equipment

- Standardisation

- Medical Software

DITTA READY TO SHARE COMPETENCES WITH AHWP

DITTA is ready to continue to support AHWP on the following topics:

- **Medical Software:** constant evolution of regulatory framework around the globe

- **Standardisation:** critical support to regulatory convergence in medical technology independently of national regulatory obligations in various jurisdictions

- **Cybersecurity:** increased focus and dedicated intelligence

- **UDI:** industry is a critical stakeholder ensuring enforcement of UDI in medical technologies around the world

THANK YOU!

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BACK-UP SLIDES

STANDARDS
OUTCOME OF WORKSHOP

- Successful workshop was attended by nearly 100 people

- Key takeaways:
  - Theme of "collaboration" throughout the afternoon
  - Inclusion of all stakeholders (especially regulators)
  - Prioritization of standards work
  - Continued education across stakeholders
  - Standards must be able to keep up with technology advances

Background-

- Medical device cybersecurity is complex and its scope involves many actors. However, some jurisdictions have begun to address it by simply issuing guidances. DITTA supports a harmonized approach, and has organized a dedicated working group to contribute to global efforts on cybersecurity.

Cybersecurity policy-

- Medical Device cybersecurity efforts must be focused on ensuring the confidentiality, integrity and availability of devices' information assets. i.e. data, functions, software.
- It has to be clear, that manufacturers' measures for cybersecurity risk mitigation can only address the networked device, not the network itself, or its users
- Regulators must leverage appropriate existing standards and regulatory requirements to advance and retain alignment cybersecurity in healthcare