MedITNet: An Assessment Framework to Improve Risk Management of Medical IT Networks

Dr Silvana Togneri MacMahon.
Supervised by: Dr Fergal McCaffery, Dr Frank Keenan
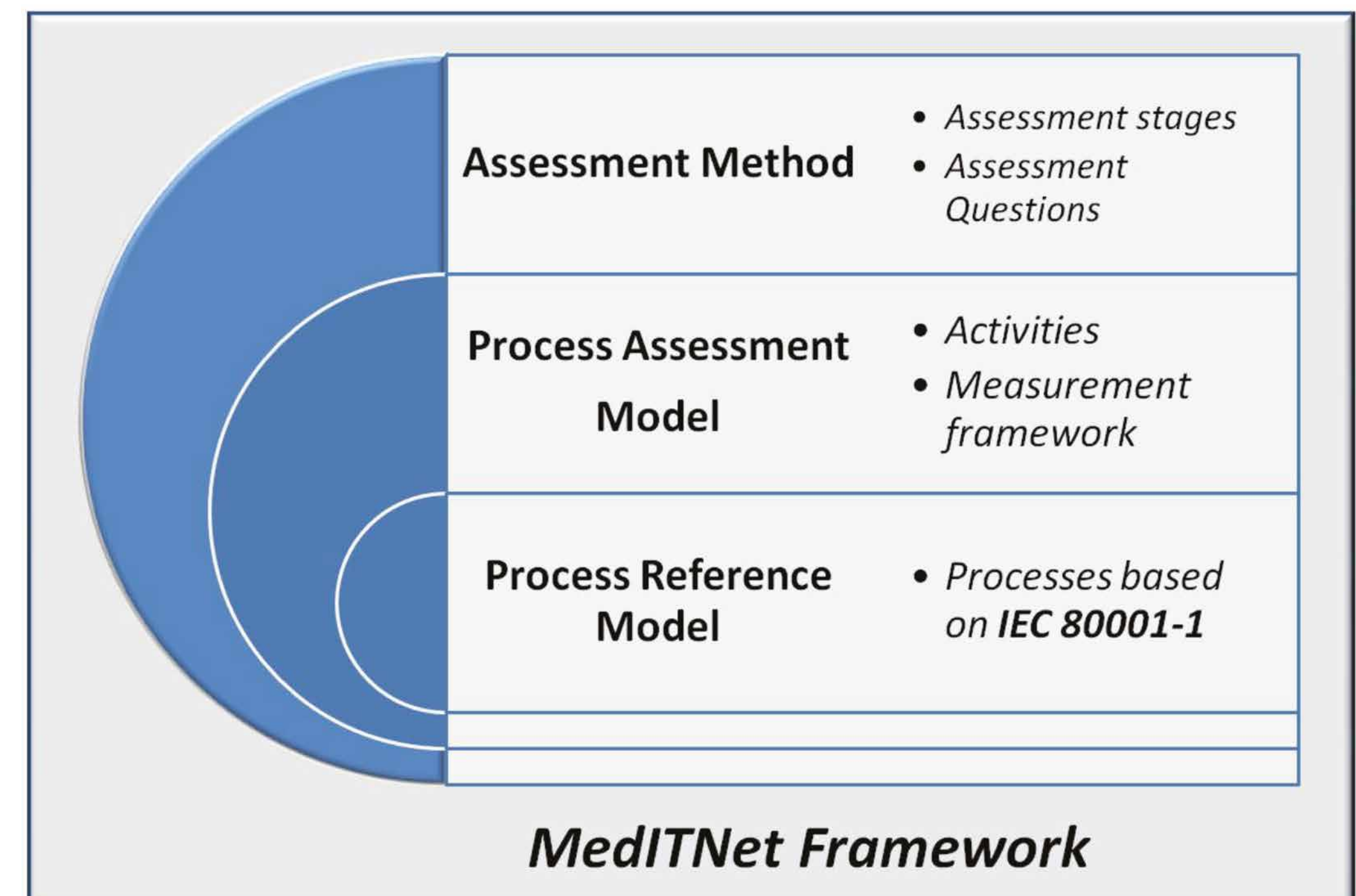
1 Research Challenge

» The use of networked medical devices can provide a number of benefits such as improved patient safety, reduced costs of care and a reduction in adverse events.

» Medical devices are moving away from the use of proprietary networks and are increasingly designed for incorporation into a hospital's general IT network enabling devices to exchange critical information.
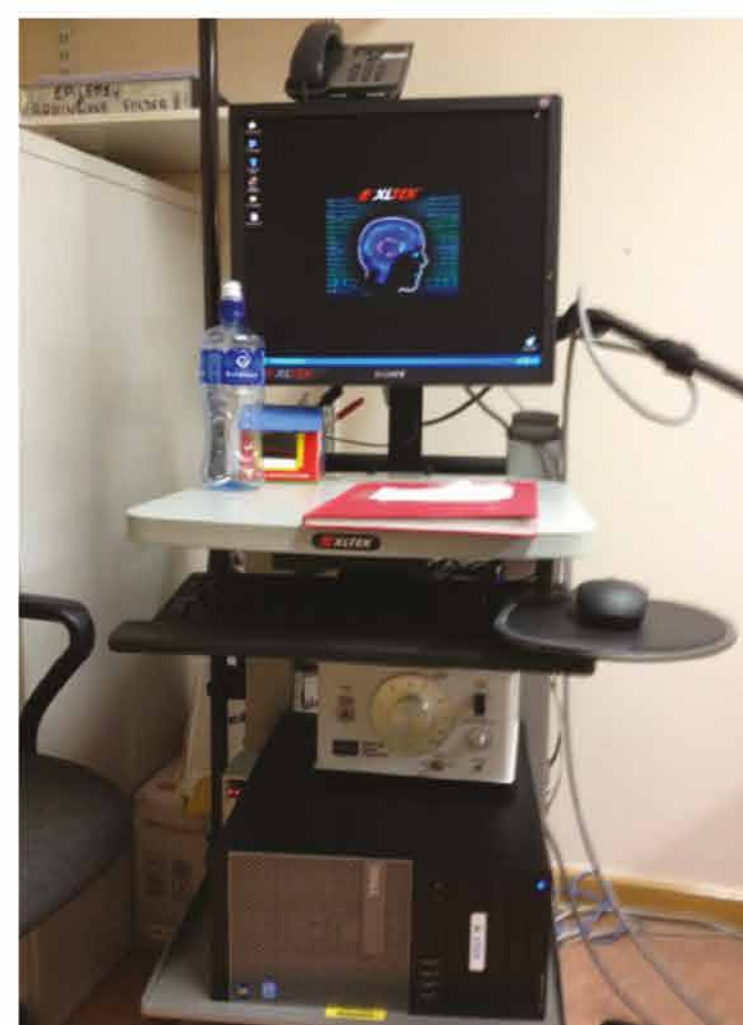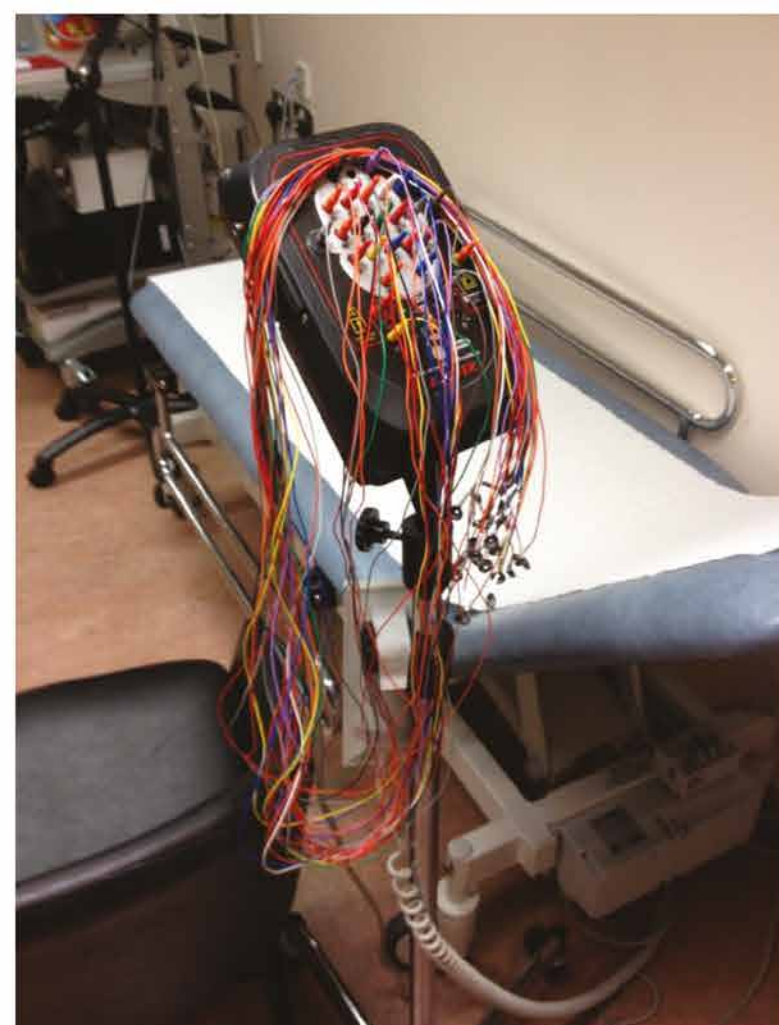
» The incorporation of a medical device into an IT network can introduce additional risks, compromising the safety, effectiveness and the security of the IT network.

» While IEC 80001-1:2010 was developed as a step towards addressing these risks, Healthcare Delivery Organisations (HDOs) face challenges when implementing the requirements of this standard.

» This research has focused the development and evaluation of an assessment framework (MedITNet) for use by HDOs to assess the capability of risk management processes relating to the risk management of medical IT networks.

2 The MedITNet Assessment Framework

| Assessment Method | • Assessment stages
• Assessment Questions |
| Process Assessment Model | • Activities
• Measurement framework |
| Process Reference Model | • Processes based on IEC 80001-1 |

MedITNet Framework

» HDOs vary in size and in terms of the capability of their risk management processes; and provide care in different regulatory environments.

» The MedITNet assessment Framework is comprised of an ISO/IEC 15504-2 compliant Process Reference Model (PRM) and Process Assessment Model (PAM) and an Assessment method

» The evaluation of MedITNet by experts in the field, combined with the use of international standards for process assessment, ensures that MedITNet can be used for self-assessment by HDOs in varying contexts

» Pilot implementation of the MedITNet Assessment Method indicated that improvements to risk management processes, within the assessed HDO, have been realised

3 MedITNet PRM and PAM Processes
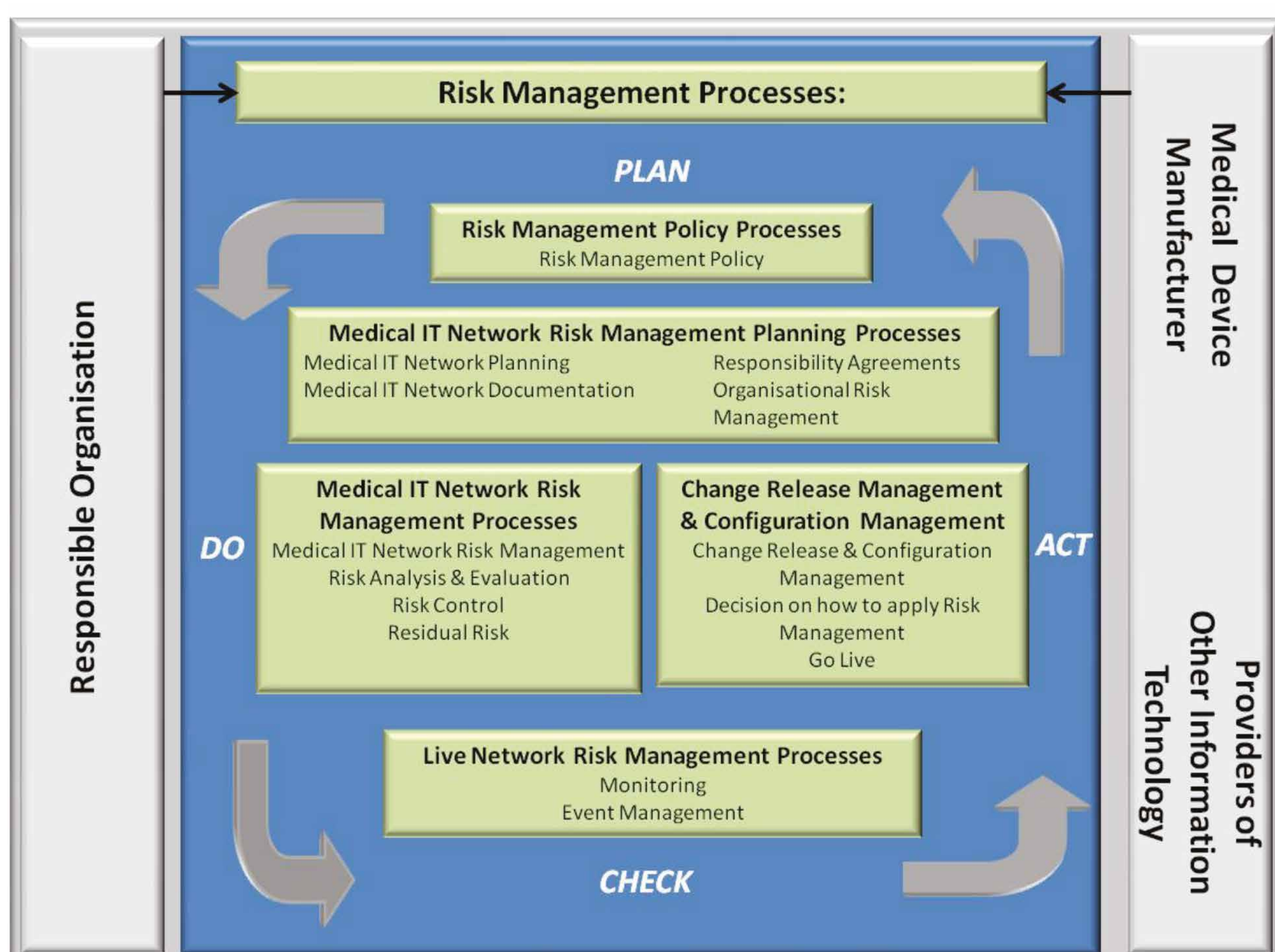
» The PRM and PAM contain 14 processes addressing various aspects of Risk Management during the lifecycle of the Medical IT Network

» A "Plan, Do, Check, Act" approach has been taken

» The Responsible Organisation, Medical Device Manufacturer and Providers of Other Information Technology are involved in the performance of risk management activities throughout the lifecycle.

» Risk management activities aim to protect the three key properties of the network: Safety; Effectiveness; and Data and System Security

4 Using Action Design Research
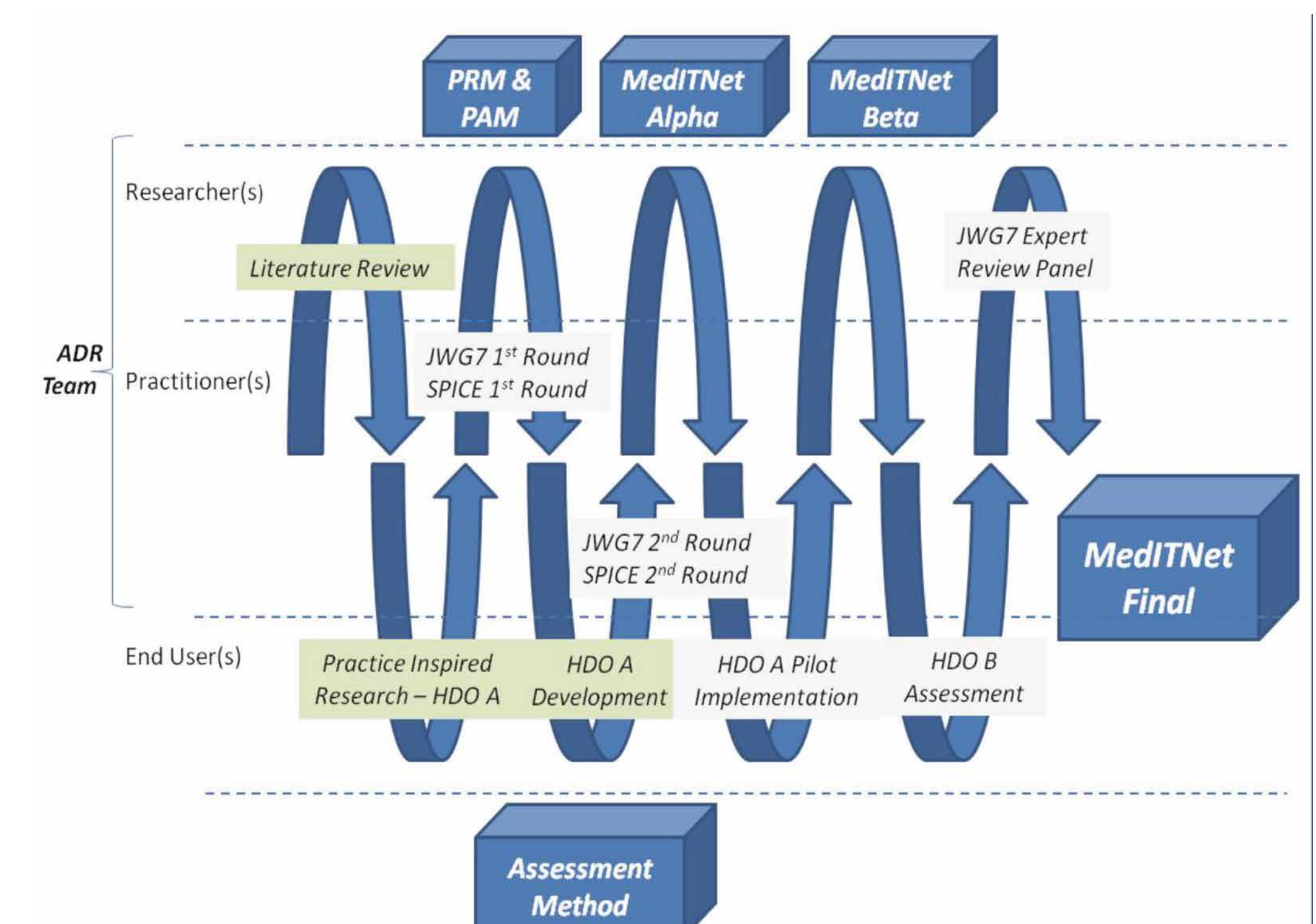
» All components of the MedITNet framework have been developed and validated using Action Design Research

» Components have been iteratively validated by international experts responsible for the development of IEC 80001-1 and risk management stakeholder in a HDO

Acknowledgments