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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



22nd Asian Harmonization Working Party Annual Meeting



4-8 December, 2017 | New Delhi





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Benefits & Risks of Remote Monitoring: Regulatory Considerations across Jurisdictions

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December 6, 2017





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Remote Monitoring Topics

- What is it?
- Examples of remote monitoring
- Benefits
- Managing Risks
- What is MDDS?
- Regulatory considerations





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Remote Monitoring: What is it?

The ability to monitor patients with implanted products using Internet connectivity

Typical components of a Remote Monitoring System:

- *Programmer in Physician's Office*
- *Patient Care Network*
- *Implanted Device*
- *Unit used to transmit data*





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Example #1: Merlin Remote Monitoring System

- Provides remote monitoring for patients with RF ICDs and RF pacemakers
- The Merlin System also enables:
 - Real-time detection, automatic alerts and early intervention by the physician
 - Nightly diagnostic readings of the device
 - Unscheduled transmissions based on predefined alerts





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Benefits: Merlin Remote Monitoring System

- Provides early detection and better AF management
 - Reduction in health care visits
 - Earlier detection of actionable events
 - Streamlined communication between patients and physicians
- Can detect possible lead failures and send notification to the physician
- Will check for high current early during the HV shocking process
 - If high current is detected, therapy is aborted





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Example #2: CardioMEMS™ HF Monitoring System

- Proven to significantly reduce Heart failure (HF) hospital admissions and improve quality of life in NYHA class III patients
- Utilizes a pulmonary artery pressure sensor, a home electronic system and website for HF patient monitoring





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Benefits: CardioMEMS™ Remote Monitoring System

- Allows physicians to see small but meaningful changes - then make medication adjustments to stabilize the patient
- Provides early detection and better HF management
 - Fewer hospitalization events per patient per year
 - Shorter length of hospital stay
 - Lowers hospitalization costs per patient per year





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Summary of Remote Monitoring Benefits

- Patient convenience
- Improved quality of life
- Clinical convenience
 - Automatic scheduling using remote care
- Clinicians have un-interrupted data
 - Monitor disease status and device performance daily
- Data automation reduces data entry errors
- Improved efficiency and reduced cost





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Managing Risks: Patients

- Reduces risks through early detection
 - Early detection leads to early intervention
 - Alert notifications reduce the time to a clinical decision
 - Early intervention improves outcomes
- Reduce risks through ease of use
 - Customizable messages to patients
 - ✓ Call Clinic (for further instructions, med changes, etc.)
 - ✓ Reading reminder
 - ✓ Reading reviewed





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Managing Risks: System

- Must maintain secure transfer of data
 - Data is typically transferred back to initiating country, then to physician
 - Validation of data transfer in multiple countries
- Cybersecurity
 - Cybersecurity-embedded designs
 - Constant threat and risk analysis testing
 - Protection from near-field communication





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What is an MDDS?

- A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses:
 - The electronic transfer of medical device data
 - The electronic storage of medical device data
 - The electronic conversion of medical device data from one format to another format in accordance with a preset specification, or
 - The electronic display of medical device data





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What is not an MDDS?

- General purpose IT infrastructure
 - Routers, hubs, wireless access points
 - Network attached Storage
 - Networks used to maintain medical devices
 - PDF Software
 - Standard IT software
 - Computer monitors





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How are MDDS devices regulated?

- MDDS devices are Class I in the US
 - No 510(k), PMA-S, or annual reports are required
 - Changes can be made without a regulatory submission/approval
- Considerations
 - Software that includes functionality that is MDDS along with functionality that is not MDDS, may result in a higher device classification





Classifying a product as MDDS?

- Is the device intended to be relied upon in deciding to take immediate clinical action?
- Is the device modifying or interpreting the data it transfers?
- Is the device initiating a signal that turns on a Class III function?
 - If the answer is yes to any of the above questions, it is not an MDDS



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Regulatory Considerations

- Ensure secure transmission of data to the physician
- RF band must be approved in the country you are seeking approval in
- Must meet Radio Regulations in each country
- Cybersecurity becoming a requirement for product approval
- Reimbursement challenges





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Conclusion

- **Early detection saves lives**
- **Remote monitoring enables early detection and intervention**
- **Work with regulators to understand the evolving requirements for remote monitoring devices**





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Thank-you

